

## Revised Requirements for the Domestic Licensing of Special Nuclear Material (Part 70)

### Comments in Document Library

Source	Citation	Comment	Response
NEI letter (042-0036), 11/4/98, on chemical safety.	Attachment 1 presents the changes that NEI recommends be incorporated to accurately reflect NRC's regulatory jurisdiction over hazardous chemicals.	1.The breadth of this jurisdiction exceeds that described in SECY-98-185 and in the 1988 NRC/OSHA Memorandum of Understanding (MOU).	Agree. Rule was revised to reflect MOU. New 70.60(b), (c), and 70.62(c) wording and defn., "Haz. chem..." parallel MOU.
		2. (i) The term " <i>hazardous chemicals</i> " should be replaced by " <i>radioactive materials or hazardous chemicals produced from radioactive materials</i> " This change would apply to §70.60(b)(1)(ii)(B), §70.60(b)(1)(iii)(c), §70.60(b)(2)(i)(B) and §70.60(b)(2)(ii)(B) of the draft rule and throughout SECY-98-185.	Agree. Language adopted (except uses "licensed" materials as opposed to "radioactive" materials.
		2. (ii)The proposed Rule revisions could be simplified by retaining references to the AEGL and ERPG standards, but deleting the actual tables of exposure limits which will be continually updated and modified.	Agree in part. AEGL/ERPG references removed from rule (will be in SRP); equivalent, qualitative language adopted in 70.60(b) & (c).
		2.(iii) " <i>Hazardous Chemicals</i> " definition should read as follows: " <i>Hazardous Chemicals means substances that are toxic, explosive, flammable, corrosive or reactive to the extent that they can endanger life if not adequately controlled.</i> "	Comment not applicable. Definition <i>hazardous chemicals</i> deleted from 70.4.
		2(iv) Add definition for " <i>Hazardous Chemicals Produced from Radioactive Materials.</i> " The new definition should build upon the existing definition of Hazardous Chemicals and should read: " <i>Hazardous Chemicals Produced from Radioactive Materials means Hazardous Chemicals either having radioactive material(s) as precursor compound(s) or formed through interaction with radioactive materials. They do not include chemicals merely added to, or used in, or recycled from, the processing of special nuclear material (SNM).</i> "	Agree. Added a definition of <i>hazardous chemicals produced from radioactive materials</i> that is similar to comment

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NEI 11/25/98 letter (042-0043). SRP New Programmatic Criteria	Cover letter, p.1	New prescriptive, programmatic criteria introduced in the SRP without any specific basis in 10 CFR Part 70 will become <i>de facto</i> regulatory requirements.		Disagree. The intent is to use the SRP as guidance only.
	Cover letter, p.2	The prescriptiveness of the draft SRP language is of particular concern. Though possibly not intended, it often appears to prejudge the need to implement new programs and practices before an Integrated Safety Analysis (ISA) establishes their need.		Disagree. The intent of including these topics is to be inclusive. The applicant, based upon his ISA, may find that a lesser grade or no program is sufficient.
	Cover letter, p.2	More clearly distinguish between what information is expected in a license application for a new fuel cycle operation versus that required for the renewal of an existing license, the guidance provided to the NRC reviewer in the SRP might be different and more in line with the current industry proposals.		Disagree. In general, outside of addressing baseline design criteria, the reviewer would be expected to consider the same areas.
	Enclosure, Section I	NEI also anticipated that the NRC would permit licensees to determine, based on the results of their own Integrated Safety Analyses (ISA), whether any changes would be required in their existing programs, procedures and practices in order to provide reasonable assurance that the consequences of concern set forth in §70.60(B) of the rule would not be exceeded.		Agree in Part. Licensees are expected to determine whether any changes are required in their existing programs based upon the ISA; however, the NRC reviewer will evaluate the implementation to see if the implementation is appropriate.
	Enclosure, Section II	1 Quality Assurance Criteria (Draft SRP §11.3):	The SRP mandates that all 18 NQA-1 criteria are to be addressed for both high and intermediate risk accident sequences, although their application is to be graded according to risk [Draft SRP §11.3.4.3].	Agree. Clarified to show that all 18 criteria are not required.
			Imposition of NQA-1 as a requirement for compliance with 10 CFR Part 70 is a new programmatic requirement.	Agree. Added other QA options to clarify that NQA-1 was not a requirement.
			The SRP “prejudges” that a licensee’s quality program, must conform to the NQA-1 criteria.	

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			Imposition of NQA-1 on fuel facility licensees would necessitate radical changes in virtually all affected licensees' quality programs.	Disagree.
			The imposition of NQA-1 on Part 70 licensees, whether on a graded basis or otherwise, should not be injected as a new "expectation" either in an SRP, or through informal case-by-case licensing action, unless specifically included as a Part 70 rule requirement.	Disagree. NQA-1 is guidance; if included in rule it would be mandatory, which is not what NEI or NRC want.
			Reference to NUREG-1200 on "design" and "construction" activities creates QA criteria for design and construction of non-plutonium Part 70 facilities. This is a new programmatic requirement that is not consistent with licenses that have been issued. The creation of QA criteria for design and construction of Part 70 facilities is not a requirement of Part 70.	Agree. Deleted reference to NUREG-1200.
			The SRP does not address how existing licensed facilities would have to comply with these new design and construction requirements.	Disagree. Existing facilities would have to address.
			The number of NQA-1 criteria which an individual program must address – even for high and intermediate risk events – can only be established following completion of the appropriate ISA.	Agree.
	2. Training and Qualification (Draft SRP §11.4)		There is no requirement in the Part 70 rule which requires such a comprehensive level of staff training as that mandated in the SRP.	Agree in part. Training requirement is determined based on ISA.

§11.4)

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			Risk-informed, performance-based regulation grants a licensee the latitude to establish the content, detail and comprehensiveness of its staff training and qualification program. A "Systems Approach to Training" (SAT) program may not be warranted.	Agree.
			The SRP does not justify how operator knowledge and skills in "design" and "construction" activities at non-plutonium licensed fuel cycle facilities enhances health and safety.	Agree. Rule revised.
			Adoption of such standards represents a significant departure from current licensing practice and the rulemaking package does not discuss the implications of this change.	Agree in part. Clarified to show that SAT not required.
			Different training requirements may be appropriate for new fuel cycle facilities, particularly if a new process or technology is to be used where there is a dearth of operating, safety and performance history. The SRP should differentiate between the staff training and qualification requirements for new and existing fuel cycle facilities.	Agree. SRP revised to reflect that training is based on ISA, whether new or existing facility.
			The Qualifications, Training and Human Performance Requirements detailed in the SRP: (a) are very prescriptive and cumbersome; (b) are inconsistent with current industry practice; and, (c) will result in only a marginal positive impact on the effectiveness of facility training programs. Such requirements should only be established by the licensee using the results of the ISA.	Agree in part. SRP clarified to show that training requirements are based on ISA.

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		3. Fire Safety (Draft SRP §7.0)	The SRP requirement (acceptance criteria) for an “Fire Protection Program” (FPP), Fire Hazards Analyses (FHAs), and Pre-Fire Plans (PFP) constitutes a new set of programmatic requirements.	Agree in part. The SRP has been revised to clearly indicate that these concepts are guidance, and options for <i>one acceptable</i> approach, not additional requirements.
			Unless the risk of an accident sequence justifies, or a specific provision written into the Part 70 rule mandates this comprehensive level of fire safety, FPPs, FHAs and PFPs may not be warranted.	Agree. The results of the ISA will be used to determine the risks of credible accidents that include fires. An FHA is an option for including the information/concepts in the ISA. The concepts embodied by FHA and PFPs need to be considered in assessing those risks, be it in the ISA or a FHA.
			The listing of 58 NFPA codes and the statement that the “most current versions” of those codes will be utilized as the basis for Staff reviews clearly creates new regulatory expectations that may be very costly to achieve and may require licensees to continually upgrade their facilities to meet newly-developed industry codes without any commensurate reduction in risk.	Agree. Compliance with the code-of-record should be sufficient for existing facilities.

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		4. Decommissioning (Draft SRP §10.0)	At the time of license application the SRP requires submission of a detailed decommissioning plan and detailed procedures to minimize contamination to the environment. This constitutes a new programmatic requirement. By contrast, at present, licensees at operating facilities must simply submit a cost estimate for decommissioning and provide financial assurance through a decommissioning funding plan, as part of a licensing submittal.	Agree in part - The SRP is to be used for new license applications as well as amendment applications. Staff agrees that the timing of submitting a DP was not clear. Language was revised to show that DP's are not required during new license application.
			Forecasting the methodologies or technologies to be used to decommission a facility 20 to 40 years in the future is an unreasonable requirement.	Agree. This is not required by the SRP which has been revised to make clear that DPs and detailed descriptions of decommissioning tech. is only required shortly before decommissioning actions begin.
			NEI believes that this entire chapter should be removed from the SRP and placed in a Regulatory Guidance document	Disagree - The SRP is intended to consolidate all guidance documents. This chapter is necessary and should not be deleted.

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		5. Human-System Interfaces (Draft SRP §11.6)	The draft SRP requires [“formal evaluation of human-system interfaces” and requires licensees to have a formal process for “design, evaluation, implementation, maintenance, and modification of human-system interfaces . . . .” [Draft SRP §§ 11.6.3, 11.6.4.3]. This includes periodic human-system interface reviews, employment of human-system interface “specialists,” development of human-system “standards” and creation of an “inventory” of such interfaces. This portion of the SRP is a new programmatic requirement.	Agree - These requirements were removed from the rule therefore this chapter was no longer needed and was removed from SRP.
			It creates an entirely new and complex set of criteria that will require licensees to establish detailed programs and procedures to formally analyze interfaces between personnel and systems.	Chapter was removed
			Additionally, it prejudices that control of human-system interfaces is needed, regardless of the results of the ISA.	Chapter was removed
	6. Organization and Administration (Draft SRP §2.0)	Licenses issued under Part 70 are not for the construction and operation of facilities, but rather for the possession and use of special nuclear material. Therefore, specifying policies on design and construction in the SRP is unwarranted. This represents a substantial change in policy and practice.	Disagree. Although Part 70 is for the possession of special nuclear material, sometimes the method to ensure its safe use is through specifying guidance on design and construction of the facility.	

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			Second, the SRP provides for NRC Staff review of the “experience” and “availability” of personnel for decommissioning of licensed facilities [Draft SRP §2.4.3]. Again, review of such details associated with the actual decommissioning process at the licensing stage is premature. What contractors and personnel will be available in 20 to 40 years to oversee decommissioning cannot reasonably be expected to be known now.	Agree.
			Imposing licensing standards for the maintenance of a “safety-conscious work environment” goes well beyond existing practice and requirements and is inconsistent with the Commission’s February and September policy determinations.	Agree.
		7. Emergency Management (Draft SRP §8.0)	Part 70 currently does not require formal training of offsite fire, police, medical and other emergency personnel. The draft SRP appears to go beyond existing requirements.	Agree in Part. Part 70 does require the licensee to off such training, although the offsite agency is not required to accept it.
			NRC’s own analysis did not identify significant off-site risks. The draft SRP suggests an emergency response training program that is more akin to those established for commercial nuclear power plants.	Disagree. The training requirements in the SRP are no different from and have not been expanded from past practice for fuel cycle facilities.



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			Until such risks are assessed in an ISA, the components and requirements of an emergency management plan can not be accurately defined. The SRP must allow the licensee to establish appropriate emergency response measures and to determine the extent of training which should be provided to "offsite emergency response personnel."	Agree in Part. Part 70 does list some specific requirements related to the emergency management plan. However, other specifications in the SRP are guidance for the reviewer to examine, and appropriate justification for their lack of implementation is acceptable.
		8. Configuration Management (Draft SRP §11.1)	The expectation that licensees will be required to "reconstitute" their "designs" [Draft SRP §11.1.3(6), 11.1.5.26] constitutes a new programmatic requirement. Provisions for design bases reconstruction go well beyond existing requirements and, in fact, substantially exceed the requirements applied to nuclear power plants.	Agree in Part. The only expectation is for the licensee to ensure that their design basis documentation is current in respect to operating practice for those areas related to ISA development.
			Part 70 licenses do not "license" the design of a facility and so there should be no requirement to perform a reconstitution.	Disagree. The licensee still needs to show that the ISA is developed using current operating practices. If they have always used an appropriate configuration management program, this should not entail any additional effort.
			Operators of new and existing fuel cycle facilities should commit to a configuration management program in their licenses.	Agree.

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		9. Maintenance (Draft SRP §11.2)	The discussion of preventive maintenance specifically discusses “requalification and retraining of personnel” [Draft SRP § 11.2.4.3]. This is a unique and to the best of our knowledge, unprecedented extension of the concept of a nuclear facility maintenance program. It is not clear what additional requirements this would add over the proposed training program criteria in SRP §11.4.	Agree. Clarified to reflect that “requalification and retraining,” while important, are not part of preventive maintenance program.
			In the absence of a corresponding requirement to 10 CFR §50.65 in the Part 70 rule, the NRC should not attempt to impose a highly prescriptive maintenance program either through the SRP or as a license condition.	Agree. Revised so as not to be “highly” prescriptive.
			The draft SRP appears to require preventive maintenance and post maintenance functional tests, regardless of whether such activities are needed to ensure the proper functioning of items relied on for safety as identified by the ISA.	Agree in part. Activities are still included in SRP since they are necessary to show items relied on for safety are available and reliable.
		10. Nuclear Criticality Safety (Draft SRP §5.0)	The SRP goes well beyond accepted international and nuclear industry practice by assigning specific, quantitative, numerical frequencies to each of the two controlled parameters or controls as an acceptance criterion, presumably in order to determine that a particular nuclear criticality accident is “highly unlikely.”	Agree. This quantitative specification has been removed from the SRP Chapter.
			Adoption of these new quantitative standards will add considerably to the cost and complexity of performing nuclear criticality safety analyses.	This comment is no longer applicable because the quantitative standards has been removed.

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			In industry's view, if adherence to the double contingency protection principle is confirmed, then it follows that a nuclear criticality event would be "highly unlikely."	Agree.
	Enclosure, Section III, Conclusions	The rulemaking record is replete with explanations as to the purpose of the requirements to perform ISAs, to adopt consequences of concern, to identify items relied on for safety, and to assure that such items remain available and reliable. It does not, however, explain at all the bases for the determination that the wide range of new programmatic criteria in the draft SRP is necessary or appropriate.		The SRP was revised to make clear that the contents are guidance and not requirements.
NEI 12/17/98 letter (042-0046): criticality safety	Cover letter	NEI supports the NRC's efforts to make the Part 70 rule consistent with the ANSI/ANS-8 NCS standards. In this regard, some modification of the language of the proposed revisions is, however, required to focus on the risks, rather than the 'consequences' and 'quantified likelihood' of accident sequences that could lead to potential nuclear criticalities.		Agree. Separate criticality performance requirement in 70.61(d) uses very similar language as ANS 8.1.
		A Part 70 license should include license commitments to manage NCS in accordance with ANS-8 guidelines.		Agree in Part. Commitment to ANS-8 standards alone is not sufficient.
		It should define the broad, operational bases for a facility, within which limits the licensee may safely operate without additional NRC approval (or license amendment) and without burdensome reporting requirements.		Agree. The license and the NRC's evaluation of the facility safety basis through the ISA process will allow a licensee to operate without burdensome requirements.
		A licensee should have the latitude to focus its NCS resources on high-risk nuclear criticality accident sequence prevention and to address safety issues within a licensee's corrective action program.		Agree.

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	Enclosure Section I (a) Risk-Informed Regulation	NCS revisions to Part 70 should consider application of a risk-informed, performance-based methodology to: ! evaluate the risk (i.e. consequences and likelihood) of potential nuclear criticality accidents whether initiated by external events, process deviations or internal events	Agree. 70.61 Performance requirements clarified to allow limiting risk by reducing consequence or likelihood, as appropriate.
		! establish appropriate risk-based (graded) levels of protection to prevent nuclear criticality accidents	Agree. Separate criticality performance requirement in 70.61(d) now uses very similar language as ANS 8.1 and Prevention of criticality is stressed.
		! establish appropriate risk-based (graded) levels of assurance for items relied on for safety to ensure their availability and reliability	Agree. 70.62(a) and (d) permit grading of the safety program
	Enclosure Section I (b) Double Contingency	The draft SRP requires assignment of specific, quantitative numerical frequencies to each of the controls to determine that a nuclear criticality accident is 'highly unlikely.' To determine whether there are at least two 'unlikely', independent and concurrent process changes necessary before a criticality might occur (i.e. double contingency protection), industry has relied instead on the expertise, experience and judgment of nuclear criticality experts on a deterministic basis.	Agree. The quantification specification for double contingency protection has been removed from the SRP Chapter.
		The SRP's definition of 'highly unlikely' as a frequency of $10^{-5}$ is arbitrary and forces differentiation of $10^{-2}$ and $10^{-3}$ between two 'unlikely' events in a criticality accident scenario.	Agree. The quantification specification for double contingency protection has been removed from the SRP Chapter. The rule requires licensees to include, in the ISA summary, their definitions of "highly unlikely" and "unlikely".

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		Measuring compliance to these arbitrary, quantitative values is burdensome and problematic for both licensees and the NRC.	Agree. The SRP has been modified to allow use of double contingency protection or quantitative values.
		Quantification of NRC's expression of the principle of double contingency contradicts guidance of the American National Standard.	Agree. The quantification specification for double contingency protection has been removed from the SRP Chapter.
		NEI recommends that industry's current practice of detailed evaluation of credible accident sequences by experienced nuclear criticality engineers continue. Adherence to the ANS-8 guidance should also be continued.	Agree in Part. Detailed evaluation of credible accident sequences by experienced nuclear criticality engineers should continue. And commitment to ANS-8 standards alone is not sufficient.
	Enclosure Section I (c) Graded Level of Protection of Items Relied On For Safety	The wording of §70.60(c) should be modified to address the risk of a nuclear criticality accident (rather than its consequences and likelihood) and to assure that items relied on for safety are "...available and reliable when required to perform their safety functions," instead of continuously available and reliable.	Comment no longer applicable. Section referenced is now 70.61(d) Criticality Performance Requirement and uses very similar language as ANS 8.1.
		Section §70.60(c) incorrectly identifies only the likelihood of external events as an element of risk from a nuclear criticality accident, thereby excluding the likelihood of process deviations or other internal events as an element of the risk evaluation. The language of §70.60(c) should be clarified.	Comment no longer applicable. Section referenced is now 70.61(d) Criticality Performance Requirement and uses very similar language as ANS 8.1.
	Enclosure Section I (d) Nuclear Criticality: Quality Assurance	Draft SRP §5.4.4.1(1) incorrectly requires that all criticality safety controls be afforded the highest level of assurance, while §70.60(d)(3)(vi) and draft SRP §5.4.4.1(5) correctly require the assurance level be commensurate with the importance of the safety function.	Comment is no longer applicable. SRP has been revised to allow grading of criticality safety controls.

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		The highest level of assurance would not necessarily be warranted for criticality controls in accident scenarios with double contingency protection.	Agree.
		The reliability of individual controls should be considered when determining the appropriate level of assurance for criticality safety controls.	Agree.
	Enclosure Section I (e) Historical Nuclear Criticality Data	As the NRC has on file, or available to them, voluminous information on all operational events, including nuclear criticality safety deviations, NEI sees little justification in submitting this information at the time of license application or renewal. NEI recommends that §70.65(c) be deleted from the Part 70 revisions.	Agree - The requirement to submit information on operational events which had a sign impact on the safety of the facility was removed. This information is already available to NRC.
	Enclosure Section II	NEI recommends that the proposed revisions of 10 CFR 70 be clarified to reduce their ambiguity and the possibility of interpreting them to be 'consequence-based' rather than 'risk-based' regulations.	Agree. 70.61 Performance requirements clarified to allow limiting risk by reducing consequence or likelihood, as appropriate.
		The rule should permit industry to continue implementation of the double contingency principle as it has done without imposition of a probabilistic methodology.	Agree. The Rule permits implementation of the double contingency principle as is currently being performed by industry.
		Part 70 should be consistent with American National Standard 8 that upholds the basic definition of the double contingency principle as adequate and sufficient.	Agree. Criticality Performance Requirement in 70.61(d) uses very similar language as ANS 8.1 and prevention of criticality is stressed.
		In support of risk-informed, performance-based regulation, the rule should grant a license applicant the flexibility to implement graded controls (and assurances) based on the results of the ISA.	Agree. 70.62(a) and (d) permit grading of safety program based on the item's importance to reducing risk

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Dec. 2, 1998 letter (042-0048) LANL ESH-6-98-A DM-05	<b>“Risk informed and performance based regulation”</b>	Numerous uses of the term ‘consequence criteria’ [as opposed to risk].	Agree. Performance requirements is the term now used throughout the rule. The specific performance requirements are risk-informed and appear in 70.60(b)-(d).
		The attempt to have PRA or any other form of quantified risk assessment become a major part of the safety basis of nuclear criticality safety at any facility would be inappropriate at best. The data on which to base failure rates simply do not exist	Agree. Rewrite of SRP Chapter 5 explicitly does not require PRA or quantitative risk assessments for criticality evaluations.
	<b>70.62 ISA Requirements</b>	As a direct result of a criticality accident being labeled a ‘high-consequence’ event, there are potentially severe implications in the rule on required actions and documentation compared to how the DOE regulates criticality safety, the latter being consistent with the guidance and philosophy found in the ANS-8 standards.	Agree. 70.60 (d) now uses very similar as ANS 8.1. Criticality is no longer labeled a “high consequence event.”
	<b>“(B) For new processes submit the results of the ISA and any revisions as part of the application for amendment of the license under 70.34.”</b>	Concern that time delay inherent in compliance with this would result in enormous costs at no practical risk reduction. DOE does not review and approve criticality safety evaluations before the contractor can implement operations unless an Unreviewed Safety Question (USQ) is found.	Agree in part. Pre-approval by NRC of changes is addressed by 70.72, which has been completely revised. Only changes which result in changes to the safety (licensing) basis need pre-approval.

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	<p><b>“70.64 Baseline design criteria....</b>  <b>“(a) Licensees shall maintain..... unless.....not relied on for safety.</b>  <b>“(1) Appropriate records of these items must be maintained..... throughout the life of the facility.</b>  <b>“(2) ... “</b></p>	<p>What does this mean? Would it include cans and process equipment such as 5-liter dissolution pots, 4-liter Erlenmayer flasks, 7-liter filter boats, etc. that are not fixed in place on a glovebox floor and that truly do provide meaningful criticality protection? What if there are several barriers to reaching the critical state, a combination of vessel geometry and administrative controls such that none are dominant as is the case in many DOE operations?</p>	<p>Agree in part. Rule rewrite makes it clear that the baseline design criteria apply only to major facility-level or systems-level changes (i.e., new <u>processes</u> that require NRC pre-approval). The examples given are component-level (possibly systems-level) changes that could be addressed through 70.72 without NRC pre-approval, even if the specific equipment is an “item relied on for safety.”</p>
	<p><b>Appendix C to part 70 - Reportable Safety Events</b>  <b>“II(4 hours)....a deviation from safe operating conditions..... has the potential, as identified in the ISA,....”</b></p>	<p>Not possible to include all gradations of upsets in ISA. Within the DOE there is the flexibility to use a graded approach such that the process upset can be judged to be of such little significance locally and of such little learning value globally that it is recorded and tracked internally only. The consequences of not using this common sense approach have been painfully and expensively documented within the DOE!</p>	<p>Agree in part. Reporting requirements have been revised.</p>



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	<p><b>“Standard Review Plan, Chapter 5</b></p> <p><b>“5.4.6 ISA Results</b></p> <p><b>“The nuclear criticality aspects of the applicant's ISA are acceptable if the following criteria are met:</b></p> <p><b>“1. The applicant conducts and maintains an ISA that identifies specific control parameters....”</b></p>	Should this requirement be interpreted to mean that controls for every operation or process are identified in the ISA? If so, either the ISA would be continually out of date or the DOE contractors nationwide would be shut down. Due to hundreds of independent operations, processes and limits in larger facilities are changing weekly if not daily in some cases.	Disagree. The purpose of the ISA is to identify the hazards at a facility as well as the controls which prevent or mitigate these hazards. these controls must be identified so that they can be maintained and remain available and reliable as specified in the regulations.
	<p><b>“7. a. At least one of the two controlled parameters...”</b></p>	This implies that there are only two controlled parameters, a very rare situation, and implies a misunderstanding of the double-contingency principle.	Comment is no longer applicable. SRP has been revised.
	<p>“5.4.5.2 NCS Limits</p> <p>“5.a controlled parameters:</p> <p>When using experimental data, the applicant applies industry-accepted safety factors.....45%....75%....etc.”</p>	These ‘industry-accepted’ safety factors were never adopted by ANS-8, nor are they in any refereed publication. In fact I have no idea where they are documented except possibly in NRC guidance for licensees. The DOE has no such formal, specific limits since there is no indication that they would reduce accident frequency; they would clearly have a tremendous cost impact on many DOE sites.	Disagree. These values are found in current licenses based on industry data from experiments.

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	<p>5.5 Procedures for Review</p> <p>“5.5.2 Safety Evaluation</p> <p>“14. The reviewer will determine that ... maintains a NCS review of the ISA ...that includes a review of identified potential accident sequences that result in an inadvertent nuclear criticality.”</p>	<p>This does not state a ‘representative worst-case’ criticality scenario and thus it implies that this will be maintained for every operation in the ISA. This is contrary to the safety analysis guidance for DOE facilities and would be prohibitively expensive.</p>	<p>Agree. The licensee’s ISA process will allow a licensee to operate with a current safety basis.</p>
<p>Dec. 1, 1998, letter (042-0049) from NCSD/ANS</p>	<p>Proposed 10 CFR 70.60(b) defines a nuclear criticality as a "high consequence" event.</p>	<p>The category of "high consequence" for a criticality accident should be consistent with the other events in this category and be limited to those accidents for which an exposure of over 100 rem is likely.</p>	<p>Agree. 70.60 (d) now uses language very similar to ANS 8.1. Criticality is no longer labeled a “high consequence event.” The separation means that the Rule does not equate a criticality to any particular dose.</p>

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	The direction and bases provided in the SRP Section 5.4.5.2 for establishing nuclear criticality safety limits for controlled parameters and their respective controls is overly prescriptive, onerous, and confusing.	As properly validated and applied, the subcritical value of $k_{\text{eff}} \leq k_{\text{failure}}$ should have no less certainty for defining a subcritical condition than an actual critical experiment. This is to say, that the selection of operational controls should be independent of the methods (i.e., experimental data versus validated analytical methods) used to establish parameter limits. Thus, we conclude that the Controlled Parameters and Controls methodologies in Subpart 5.b are inappropriate.	Comment is no longer applicable. SRP has been revised such that the methodology used does not affect the results.
	The SRP essentially requires the use of the probability risk assessment (PRA) method to determine if the double contingency principle is affirmed.	Concerned that more effort will be expended in calculating the probabilities than in demonstrating that the entire process is in fact subcritical as required by Section 4.1.2 of ANSI/ANS-8.1. Data bases simply do not exist to support PRA for equipment failures in fuel cycle facilities and we feel that this course of action could divert attention from operational safety.	Agree. The quantification specification for double contingency protection has been removed from the SRP Chapter and so PRA or quantitative risk assessments for criticality evaluations are not required.
	In principle, we support the integrated safety assessment (ISA) process proposed by the 10 CFR Part 70 rule change.	The reporting requirements appear to be quite burdensome. For example, DOE requires contractors to have criticality safety evaluations for all operations, but reporting is not required if the operations remain within the operating bases authorization. The NRC should consider this model.	The reporting requirements were revised to require reporting when criticality controls are lost.

Source	Citation	Comment	Response
NEI 12/22/98 letter (042-0053) on ISA & preliminary ISA	Cover letter	<p>The results of the ISA should not be included in the license. The onus be placed on a licensee to perform and implement an ISA, the licensee commit to maintaining an updated and complete version of the ISA at the licensed facility and only a summary of the ISA results be provided to the NRC for placement on the docket.</p> <p>! Materials License: would contain the licensee's commitments to conduct, maintain, implement and update the ISA</p> <p>! ISA Summary: a synopsis of the results of the ISA would be submitted to the NRC for placement on the docket. This synopsis would outline the ISA methodology, identified high-risk accident sequences, implemented mitigative safety controls and control assurances.</p> <p>! Complete ISA: would be maintained at the licensed facility for NRC inspection and for updating as the facility (or its processes) are modified.</p>	Agree with this concept. The safety program information is specified in 70.62 and is maintained on site. The ISA summary is specified in 70.65, it is not part of the license but is submitted on the docket and reviewed with the license.
		NEI recommends that preliminary Process Hazards Analysis (PHA) terminology be used in the Part 70 revisions. A preliminary PHA would be submitted to the NRC at the conceptual engineering phase of the project. NRC could use the preliminary PHA for informational purposes, acknowledging that the process or facility design may undergo refinements and redesigns prior to its eventual construction and commissioning. The licensee's ISA would be based on the "as-built" facility and would incorporate some, if not all, of the results of the preliminary PHA.	Agree. Conforming change made. Note NEI comment of 3/26/99 changed this position, requesting (1) deletion of the PHA definition (taken), (2) PHA be performed but not be required to be submitted (taken); and (3) the word 'analysis' be replaced with 'evaluation' (Not taken).
	(a) Risk-Informed Regulation	Part 70 revisions should discuss the risk of an accident sequence rather than separately its consequences and likelihood.	Agree. The performance requirements in 70.60 have been clarified to permit limiting risk by reducing either consequence or likelihood, as appropriate

Source	Citation	Comment	Response
	(b) Inclusion of ISA in License Application	<p>! Complete ISA: The detailed results of the ISA would be retained by the licensee at the facility to be used to safely manage it and to be available for NRC licensing reviews and compliance inspections. The ISA would be updated under the facility's Configuration Management Program as modifications to the facility or to processes are implemented.</p> <p>! ISA Summary: A synopsis of the results of the ISA would be prepared and submitted to the NRC for placement on the docket. The ISA summary would identify the disciplines of expertise and minimum qualifications of the individuals who performed the ISA, outline the approach and methodologies used in performing it, describe any identified, credible accident sequences whose unmitigated consequences could exceed the consequences of concern in ¶70.60(b), the safety controls implemented to reduce the risk of such accidents and the measures used to ensure the availability and reliability of such controls. The ISA summary would be maintained as a reference on the licensing docket or as the safety demonstration in Part II of a traditional two-part license. It would be revised on an annual basis.</p> <p>! Materials License: A license applicant's commitments to conduct, maintain, implement and update the ISA would be the only commitment required to be included in the license.</p>	<p>Agree in part with the concepts in these statements. However, in the last bullet, it is not true to state that commitments to conduct, maintain, etc. the ISA are the "only" commitments in the license (e.g., licensees must show how they comply with Part 20, which is outside the scope of the ISA).</p> <p>As Stated previously, 70.65 which contains the required contents of the ISA summary has been revised to follow the basic concept presented by NEI. The summary would also be on the docket and not in the license.</p>
		Licensees would be free to change their facility or process configurations in accordance with their approved internal change control process without prior NRC approval or license amendment.	Agree in part. Changes to the facility would still need to meet the requirements of 70.72.

Source	Citation	Comment	Response
		<p>The following definition of an ISA summary is proposed for inclusion in §70.4 of the proposed revisions to Part 70:</p> <p>“ISA summary means a synopsis of the results of the ISA that succinctly describes the facility or its processes, identifies the disciplines of expertise and minimum qualifications of the individuals who performed the ISA and outlines the approach and methodologies used in performing it. The ISA summary identifies and describes those credible accident sequences, whose unmitigated consequences could exceed the consequences of concern elaborated in §70.60(b), the safety controls (or items relied on for safety) to mitigate the risk of such accidents to an acceptable level and the measures to ensure the availability and reliability of such controls. The ISA summary shall be placed on the docket and shall be updated annually by the licensee, but shall not constitute part of the license.”</p>	<p>Agree in part. Consistent with a subsequent NEI comment, the definition the staff eventually adopted in 70.4 simply refers to 70.65, which lists the detailed contents of the ISA summary. There was no need to repeat the same information in the definition.</p>
	(c) Decommissioning ISA	<p>NEI recommends that §70.62(b) be deleted from the proposed Part 70 revisions. NEI believes that a separate decommissioning ISA is not warranted. The facility’s existing ISA program can be used to assess the potential hazards of activities and procedures proposed for use in the decommissioning phase. Any required changes to the ISA and facility operations to protect the health and safety of workers and the public during decommissioning can be implemented within the framework of the existing ISA program.</p>	<p>Agree. Current relevant Section is 70.60. ISA does not apply to decommissioning, which is addressed by existing Part 20, 70.25 &amp; 70.38</p> <p>Agree - The requirement to perform decommissioning ISA was removed. An additional sentence was added that stated facilities must meet all other decommissioning requirements in Part 20 and 70.</p>

Source	Citation	Comment	Response
		The example cited in the draft language for §70.62(b)-- "...potentially hazardous activities such as chemical treatment of wastes..." -- may be inappropriate as the NRC-OSHA MOU does not grant NRC jurisdiction over management of purely chemical wastes.	Comment no longer applies based on acceptance of comment to delete decommissioning ISA
	(e) Preliminary ISA (or Process Hazards Analysis)	NEI recommends that the PHA terminology be used throughout the proposed Part 70 revisions and that the following preliminary PHA definition be included in §70.4 of the rule:  "Preliminary Process Hazards Analysis (PHA) means an analysis undertaken during the design or early development phases of a process to identify the principal potential hazards and to enable them to be eliminated, minimized or controlled with minimal cost or disruption. The analysis also assists in identification of potential corrective, mitigative or preventive measures."	Comment no longer applies. NEI subsequently commented that the requirement to submit the preliminary ISA (or PHA) be deleted. That comment accepted by the staff.
	(f) Persinko Chart	Some clarification of the wording in the right-hand column of the chart is recommended.	Comment no longer applicable. Chart has been abandoned.
	Concluding Remarks	ISA be used in the licensing process in three ways: ISA commitments in the license, ISA summary on the docket and active management of the complete ISA at the licensed facility.	Agree. Reflected in rule.
		NRC licensing and regulatory resources be focused on those high-risk accident sequences that could potentially have the greatest impact on the health and safety of workers and the public.	Agree. Reflected in rule.
		AIChE terminology for a preliminary hazards analysis be substituted for "preliminary ISA."	No longer applies - see above.
		A separate "decommissioning ISA" is not warranted.	Agree - see above.

Source	Citation	Comment	Response
NEI 1/26/99 letter (042-0058): reporting requirements ; change mechanisms; baseline design criteria	Cover letter	The existing incident reporting provisions in 10 CFR 20 and 10 CFR 70 are adequate for ensuring that the NRC is promptly informed of all safety-related incidents. Adding a new §70.74 to the existing §70.50 and 10 CFR 20 reporting requirements appears to be unnecessary.	Disagree. Although the reporting requirements in Part 20 still apply, additional requirements were necessary to conform to the new rule language.
		NEI proposes a change mechanism that would require NRC pre-approval only when that change could potentially threaten to degrade the effectiveness of a safety commitment in the license.	Disagree. A change mechanism has been developed which specifies criteria when pre-approval is required. NEI does not disagree with these criteria.
		Inclusion of baseline design criteria in the Part 70 licensing process is appropriate for new facilities. We do not, however, believe an existing fuel cycle facility should be subject to such criteria, either now or when application is made for renewal of its license. The criteria should, similarly, not apply to new processes or technologies installed at existing facilities.	Disagree. The design basis criteria are considered to be basic design tenants that are applicable to all new larger scale modifications whether or not being added to an existing facility.
	Enclosure: I. Reporting Requirements (§70.74) - (1) Adequacy of Existing Rules	Reporting requirements for fuel cycle facilities (10 CFR 20.2201-22.06 and 70.50) are already adequate; a new rule chapter is unnecessary. The need for modifying the current Part 20 and 70 reporting requirements and for including §70.74 and Appendix C in the rule, is not apparent.	Disagree. Although the reporting requirements in Part 20 still apply, additional requirements were necessary to conform to the new rule language.
	Enclosure: I. Reporting Requirements (§70.74) - (2) One-Hour Reporting	The new one-hour reporting time frame for certain events is too restrictive. The justification for shortening the reporting period to one hour for an incident which §70.50 or §20.2202 now only requires a four-hour notification is not apparent.	The one-hour reporting requirements have been revised and do not conflict with §70.50 and §20.2202. The requirements in §70.50 and §20.2202 still apply.
		NEI is particularly concerned with the exhaustive list of information that must accompany a one-hour telephone notification to the NRC Operations Center.	The information to accompany a one-hour report has been revised to conform with §70.50 information.



Source	Citation	Comment	Response
		Some required information such as personnel radiation exposure data and chemical analyses of licensed material or hazardous chemicals produced from licensed materials ((11V.(c)(3)) can not be provided within such a short time frame.	The information to accompany a one-hour report has been revised to conform with §70.50 information.
		The risk of providing the NRC with inaccurate preliminary information, which may in turn be publicly disseminated, is increased under the draft rule revisions.	Disagree. The information to accompany a one-hour report has been revised to conform with §70.50 information.
		During the first hour following a 'safety-significant' event the licensee must focus all its efforts on emergency response activities.	The information to accompany a one-hour report has been revised to conform with §70.50 information.
		NEI recommends that the one-hour time frame be limited to notification of the NRC of serious safety incidents and that all supplemental information be provided within the existing four or twenty-four hour reporting periods.	Agree. The one-hour reporting requirements have been revised to require reporting of only serious safety incidents. The information to accompany a one-hour report has been revised to conform with §70.50 information.
	Enclosure: I. Reporting Requirements (§70.74) - (3) Chemical Exposure Reporting:	Appendix C Sections I(a)(2)(ii), I(a)(3)(iii) and II(a)(1)(iii) and II(a)(2)(ii) should be appropriately corrected to correspond to the Part 70 revisions proposed by the NRC in December 1998. A licensee should not be required to report all personnel hazardous chemical exposures	Agree. The reporting requirements have been revised such that licensees are not required to report all personnel hazardous chemical exposures.

Source	Citation	Comment	Response
	Enclosure: I. Reporting Requirements (§70.74) - (4) Environmental Monitoring Program	Compliance with Appendix C ¶II(3) could be interpreted to require explicit, continuous, radiological monitoring and surveying of radiation levels in the unrestricted and controlled areas adjoining a licensed facility. Fuel cycle facilities have very benign impacts on the public. A licensee should not be required to conduct continuous radiological monitoring in the unrestricted or controlled areas of its facility.	Agree. The reporting requirements have been clarified to reflect that continuous radiological monitoring in the unrestricted and controlled areas is not required.
	Enclosure: I. Reporting Requirements (§70.74) - (5) Subjective Language	Emergency reporting of 'potential deviations' from safe operating practices or 'potentially unsafe conditions' should not be required. This language is too subjective.	The language has been revised to remove this subjective language.
		Appendix C ¶II(2)(b), ¶III(a), ¶III(c) and ¶IV(a) require notification to the NRC of "...deviations from safe operating conditions..." What constitutes a 'deviation' is not defined.	The reporting requirements have been revised and no longer use this term
		Reports to the NRC should be limited to 'deviations' that are safety-significant or that resulted in an accident. Reporting potential unsafe conditions should not be necessary.	The reporting requirements have been revised and do not require reporting of potential unsafe conditions.
	Enclosure: II. Change Mechanism (§70.72)	A licensee should have the flexibility to operate within the 'regulatory envelope' of the commitments and authorized activities contained in its license.	Agree - The 70.72 change process was revised to allow the license greater flexibility to make changes without NRC pre-approval.
		A licensee should be able to implement changes so long as they do not substantially degrade or decrease the effectiveness of any safety commitment in the license, do not approach or exceed a §70.60(b) consequence of concern, do not impair the licensee's ability to meet applicable federal regulations or do not conflict with any license conditions.	Agree in part. Section 70.72 was revised to require NRC pre-approval for the significant changes to the facility.
		The inherently qualitative nature of the ISA used to establish whether or not NRC pre-approval is needed for a change makes assessment of what constitutes "...a minimal increase..." a highly subjective call.	Agree - The change process was revised to remove the subjective wording.

Source	Citation	Comment	Response
		The onus would be placed on the licensee to identify and analyze the significance of potential hazards associated with a proposed change and to seek NRC pre-approval of a change whenever its analysis so dictates.	Agree in part. The change process has been revised to remove the subject nature of rewording and therefore it is clear when pre-approved is required.
		<p>NRC pre-approval should be required for a change to the facility or operating procedures as described in the ISA that entails:</p> <ol style="list-style-type: none"> <li>1. exceedance of, or approach to, a consequence of concern listed in §70.60(b)</li> <li>2. activities not currently authorized by the license</li> <li>3. substantial degradation or a decrease in the effectiveness of any safety commitment in the license</li> <li>4. significant process or facility changes that either create new types of higher consequence accidents or require significant changes to the facility's environmental report prepared in accordance with 10 CFR 51</li> <li>5. impairment in the licensee's ability to meet applicable federal regulations</li> <li>6. a conflict with any license condition</li> </ol>	<p>Agree. The change process has been revised to follow this concept. Changes under Bullets 2, 3, 5 and 6 in NEI's proposal would require pre-approval by NRC without a change process. Requirements in license and regulations can not be changed without NRC approval.</p> <p>The new change process incorporated changes of the type discusses in Bullets 1, 3 and 4.</p>
		The licensing basis on which the NRC establishes compliance with the rule and base licensing action approvals should be the commitments and authorized activities contained in the materials license. These would include, for example, commitments to protect health and minimize danger to life and property, to protect against nuclear criticalities, to implement fire and chemical safety programs, to conduct personnel and environmental monitoring programs, to implement management control systems and to conduct, implement and maintain an ISA for the facility. The commitment to perform, maintain, update and address vulnerabilities identified by the ISA would constitute an important licensing basis.	Agree.

Source	Citation	Comment	Response
		All changes implemented by the licensee would be incorporated into the facility's ISA and reported to the NRC in the annual ISA update. For changes not requiring NRC pre-approval the licensee would maintain written internal evaluations that provide the bases for determining that the changes do not require NRC pre-approval.	Agree in part. Since the change process allows the licensee greater flexibility is making changes without NRC pre-approval, then those changes should be reported to NRC. The rule was revised to require changes made without NRC pre-approval that affect the ISA summary to be submitted within 90 days. All other changes within 1 year.
	Enclosure III. Baseline Design Criteria (§70.64)	Proposed revision §70.74 should be revised to exclude existing licensees from adherence to these baseline design criteria, both for their existing facilities and for changes in process technology or operating procedures that may be implemented in the future	Disagree. NOTE: INTENDED REFERENCE IS 70.64. BDCs apply to new processes and new facilities equally. Meaning of new processes is clarified. Subsequent NEI comments supercede this comment to state that BDC do apply to existing licensees if an amendment for a new process is required by 70.72. Staff agrees with that approach
Jan. 21, 1999, (042-0059) letter and mark-up of draft SRP Chapter 5, Criticality Safety	Enclosure II. General Concerns (a) Degree of Prescriptiveness	The SRP often constrains a reviewer to one approach when several are possible. For example, §5.4.5.2(5) does not acknowledge that there are several ways to calculate failure limit and safety limit $K_{eff}$ values; the SRP formulation is too specific and unnecessarily constraining.	Disagree. The SRP introduction states that other approaches are acceptable as long as they are appropriately justified by the applicant.
		§5.4.4.3 arbitrarily mandates weekly audit inspections of SNM process areas and quarterly safety audits without any justification for the selected frequencies.	Agree. SRP Chapter revised to state that other time periods are acceptable as justified by the ISA.

Source	Citation	Comment	Response
		The SRP language should avoid usage of all-inclusive language and connotations. It should not constrain a license reviewer's 'acceptance criteria' to a single approach presented in the SRP.	Agree in Part. The SRP is to be used as guidance and therefore no constraining of the approach by the SRP is expected.
		The SRP should be written at a level of detail commensurate with the ANSI/ANS-8 standards.	Disagree. ANS-8 standards alone do not provide adequate information and so the SRP allows multiple approaches and provides more detail than the standards.
		Each facility's license application should be allowed to provide a level of detail appropriate to its design features and unique characteristics.	Agree. The SRP does not prescribe any level of detail.
	Enclosure II. General Concerns (b) Graded Approach to Safety	The NRC's proposal to no longer single out a potential nuclear criticality as a 'high consequence' event is appropriate and reflects a correct application of the graded approach to safety. There are numerous examples in Chapter 5 where the graded approach should be applied. Three of these examples are: (i) §5.4.4.2 (4) performance-based training in NCS for all plant personnel regardless of their responsibilities (ii) §5.4.4.1(1) requires application of the "...highest quality assurance level...for all criticality controls..." (iii) §5.4.5.1(5) presumptively assumes that changes from a passive engineered control to an active engineered control will result in a significant increase in risk.	Agree. The SRP has been changed to permit a graded approach to safety.
	Enclosure II. General Concerns (c) Use of Probabilistic Methodologies	NEI recommends that all references to probabilistic techniques be eliminated from Chapter 5.	Agree. All probabilistic techniques have been eliminated from the SRP Chapter.
		The approach for performing evaluations of margins of safety in a system (§5.4.6) should be performed consistent with ANSI/ANS-8 guidance	Agree. The approach in the SRP is consistent with ANS-8 guidance.

Source	Citation	Comment	Response
	Enclosure II. General Concerns (d) Excessive Repetitiveness	Most chapters of the SRP contain subsections on 'Training Requirements', 'Quality Assurance', 'Management Control Systems', 'Audits, Assessments and Investigations', and 'Organizational Requirements'. Inappropriate inconsistencies would be eliminated and the SRP would be a much more user-friendly document if these subchapters were removed from each chapter of the SRP and replaced by a single chapter for each topic.	Agree. The SRP has been changed to cross-reference appropriate sections and chapters.
		Chapter 5 attempts to repeat, interpret or expand upon many topics adequately addressed in ANSI/ANS-8 standards. This is not necessary. NEI recommends Chapter 5 refer the license reviewer to ANSI/ANS-8 standards	Disagree. One purpose of the SRP is to provide NRC's interpretation and applicability of ANS-8 standards for NRC reviewers
	Enclosure II. General Concerns (e) Definition Redundancies	Definitions appear in Chapter 5 that are found elsewhere in the Part 70 rule, in the ANSI/ANS-8 standard, or in the SRP. Reference to these definitions should be made rather than attempting to redefine a term in a manner that is inconsistent with the Rule or ANSI/ANS-8 standard.	Agree. Definitions have been moved to a general glossary for the SRP.
		Redundant definitions also should be removed. For example, several terms defined in §5.4.0 do not appear to be used elsewhere in Chapter 5 (e.g. 'criticality control system').	Agree. These redundant definitions have been removed.
		Conversely, terms are used which are not defined and which are used in a manner that prompts confusion (e.g. 'safety margin').	Agree. Definitions will be provided to reduce confusion.
		The language of several definitions should be clarified to remove ambiguity. For example, the term 'adequate margin of safety' should be stated to be "adequate margin of sub-criticality" (§5.4.5.1 (7)).	Agree. Use of terms will be clarified.
		definitions of 'double contingency' and 'double contingency principle' in §5.4.0 are redundant.	Comment is no longer applicable as the terms double contingency principle and double contingency protection are now used and have different meanings.

Source	Citation	Comment	Response
		definition of 'dual sampling' is erroneous (see red-lined Chapter 5 for correction),	Agree in Part. The definition has been modified to clarify NRC's intent.
		definitions of 'items relied on for safety' contained in the rule and Chapter 5 are inconsistent	Agree. The definitions in the Rule and SRP are now consistent.
		NEI recommends that technical definitions (and acronyms) be consolidated into a single chapter of the SRP.	Agree. Definitions have been moved to a general glossary for the SRP.
	Enclosure II. General Concerns (f) Adherence to ANSI/ANS-8 Standards -- ANSI/ANS-8 References	additional requirements sought by the SRP over and above double contingency are unnecessary.	Agree in Part. Additional requirements unrelated to double contingency may sometimes be required. Also, alternatives to double contingency are also permitted.
		in those areas where double contingency is met with robust systems, there is no reason for assurance measures on such controls or controlled parameters to be 'of the highest standard.'	Agree. The SRP has been modified to more clearly allow grading of measures.
		Whenever the ANSI/ANS-8 standards are cited, specific reference to its applicable chapter and section should be cited to enable the reviewer to quickly consult the appropriate and applicable section of the standard.	Agree. To the extent possible, specific references to standards will be made.
	Enclosure II. General Concerns (g) Chapter Structure and Style	The structure of Chapter 5 often is difficult to follow. For example, the introduction to Chapter 5.3 identifies four areas of review. However, the four subsections §5.3.1-5.3.4 neither faithfully nor clearly follow how these four introductory topics are presented.	Agree. The SRP Chapter has been modified in its entirety to address structure and style concerns.
		The level of detail and 'how-to' prescriptiveness, repetitiveness of definitions and sub-topics common to several SRP chapters (e.g. management systems, training, audits, etc.) and adherence to Part 70 rule provisions substantially differ.	Agree. The SRP has been modified in its entirety to provide a better consistency between sections and chapters.

Source	Citation	Comment	Response
		Several instances occur in §5.4 'Acceptance Criteria' where controls are mentioned without there being a clear linkage back to any acceptance criterion.	Agree. The SRP Chapter has been modified in its entirety in order to ensure that linkages are clear.
		NEI recommends that the entire SRP be reviewed by technical editors to ensure consistency in language, degree of detail and structure among individual chapters prior to its final issuance.	Agree. Review by a technical editor will be performed prior to final publication of the SRP.
	Enclosure II. General Concerns (h) Breadth of License Application Review	The draft SRP prescribes a much broader and extensive review of NCS technical data than should be required. The SRP directs that detailed reviews be performed of internal NCS evaluations and assessments on specific systems and/or specific credible accident scenarios identified in the ISA. NRC reviewers should, in contrast, focus on reviewing the broader NCS program (basic commitments, adequately trained personnel, review procedures, etc.) and the specific highest risk sequences.	Agree. The SRP should focus the NCS program and high risk areas of concern.
		§5.4.5.1 states that the "...application specifies the basis of nuclear criticality for each process..." and that "...the applicant demonstrates for each system that could cause a nuclear criticality, that the system possesses double contingency..." Review of each process or system is not necessary and will be very time-consuming. Only those higher risk accident sequences reported in the ISA Summary should be reviewed at this level of detail.	Agree. The review should focus the NCS program and high risk areas of concern.
	III. Specific Concerns 5.1 PURPOSE OF REVIEW	The order in which the 4 purposes are presented should parallel the order in which they are discussed in the following subsections	Agree. The SRP Chapter has been modified in its entirety to address structure and style concerns.
		Purpose (1) of this review is incorrectly stated: the reviewer will not review all accident sequences addressed in the ISA, but only those higher risk sequences which are presented in the ISA Summary	Agree in Part. As necessary, the reviewer may review other accident scenarios in the ISA at the applicant's site.



Source	Citation	Comment	Response
	5.3.1 NCS Organizational Responsibilities	move this section to Chapter 2.0 of SRP, consolidate and remove redundancies and inconsistencies, and reference reviewer to that chapter	Agree. Only items unique to NCS will remain in the SRP Chapter.
	5.3.2 Management Control Systems for NCS	move this section to Chapter 11.0 of SRP, consolidate and remove redundancies and inconsistencies and reference reviewer to that chapter.	Agree. Only items unique to NCS will remain in the SRP Chapter.
		“2. Maintenance to ensure that controls identified in the ISA Summary as important to NCS are continually available and reliable when required to perform their functions.”	Agree.
		Change “quality assurance” term to “management measures” (here and throughout the balance of Chapter 5): “3 Quality assurance Management measures to ensure that components important to NCS are properly specified, obtained, installed, operated, and maintained.”	Comment is no longer applicable, as all references to quality assurance in this Chapter have been removed.
	5.3.3 NCS Technical Practices	NRC staff review should focus on the NCS program (i.e. basic commitments, adequately trained personnel, procedures for review to ensure adequate NCS, etc.), rather than on detailed NCSEs of specific scenarios or systems.	Agree in Part. The reviewer may need to evaluate certain high risk NCS scenarios to ensure that the NCS program is adequate.
		Replace ISA with ISA summary	Agree.
		Controls should not have to be reviewed for “...each process, system and equipment function...”, but only for those higher risk accident sequences identified in the ISA Summary. If the ISA determines that a nuclear criticality is not possible in a particular process, such a review will also be unnecessary.	Agree in Part. Occasionally, the reviewer may choose to evaluate accidents not considered “high risk” by the applicant to ensure that they are, in fact, not “high risk.”
		“2. NCS controls and control parameters limits on controls and controlled parameters to ensure that an adequate safety margin of subcriticality exists.”	Agree. However, the term has been changed to margin of subcriticality for safety in the Rule.
		Is it the intent of the NRC to perform independent technical reviews of computer code calculations? This should not be the case.	Agree in Part. There may be cases where the reviewer will evaluate the methodology of how the code will be used by the applicant.

Source	Citation	Comment	Response
		“6. Information describing implementation of special protective features, as applicable, and information describing any additional margins of <del>subcriticality</del> <del>safety</del> adopted as a result of the ISA process, for specific functions or activities.” What is the definition of “special protective features”?	No longer applicable. This item has been removed from the Chapter.
		- SEE MARK-UP OF CHAPTER 5 FOR ADDITIONAL COMMENTS -	
NEI Feb. 12, 1999, letter (042-0061): comments on proposed revisions to 10 CFR Parts 70.60 and 70.62 and on nuclear criticality issues raised at the January 13, 1999 public meeting	<b>II. Comments on §70.60 and §70.62 Proposed Revisions</b>	Definitions of ‘administrative control’ and ‘engineered control’ that are consistent with the ANSI/ANS Series 8 standards should be included in §70.4.	Disagree. These definitions are more appropriate for the different SRP Chapters because different standards (e.g., ANS-8 and NFPA) have different definitions of “administrative controls.”
	(a) Administrative and Engineered Controls		
	(b) Decommissioning ISA	A separate decommissioning ISA is not warranted as facility changes during decommissioning can be processed through a facility’s existing ISA program, just like operational changes. NEI recommends that §70.62(a)(3) be deleted.	Agree. Current relevant Section is 70.60. ISA does not apply to decommissioning, which is addressed by existing Part 20, 70.25 & 70.38
	(c) ISA Results and ISA Summary	The license should specifically contain a licensee’s commitments to safety programs, including one to conduct, maintain, implement and update the ISA. An ISA Summary outlining the ISA methodology, identifying high-risk accident sequences and implemented safety controls and control assurances would be submitted to the NRC for placement on the licensee’s docket and for use by the NRC staff in reviewing a license application. The complete ISA (‘results of the ISA’) would be maintained at the licensed facility for NRC inspection and updating when the facility or its processes are modified.	Agree, this is the approach in the rule. Generally, 70.62 specifies on-site information and 70.65 specifies submitted information (i.e., ISA summary)
		The way in which the ISA is to be used in the licensing process is not correctly portrayed in the <i>revisions-in-total</i> to §70.72.	§70.72 has been revised. Comment no longer applies.

Source	Citation	Comment	Response
		The definition of ISA Summary in §70.4 requires revision.	Comment no longer applies. Consistent with subsequent NEI comment, the definition refers to 70.65, which specifies the contents of the ISA summary
	(d) Design Basis for Items Relied on For Safety	§70.62(c)(vi) should be clarified to require detailed information only on the items relied on for safety for ISA Summary-identified accident sequences.	Disagree. The ISA (maintained on site) should assess the potential accidents for all the processes, before a decision is made if an item relied on for safety needs to be identified for that process
		Part 70 baseline design criteria would not apply to existing, licensed facilities or to changes that may be made to them in the future.	Disagree. BDCs continue to apply to new processes and new facilities equally. Meaning of new processes is clarified. Subsequent NEI comments supercede this comment to state that BDC do apply to existing licensees if an amendment for a new process is required by 70.72. Staff agrees with that approach
	(e) ISA Team Qualifications	§70.62(c)(2) is too prescriptive and does not grant a licensee the option of having contractor personnel with the desired expertise participate in the ISA. The term 'employee' should be replaced by 'person' throughout this section.	Agree. term 'employee' was replaced by 'person' throughout the paragraph
	(f) ISA Revalidation	§70.62(c)(3) is not consistent with the ISA being a 'living document'	Agree. Revalidation of ISA was deleted as unnecessary, since the 70.72 process governs the facility changes and updating of safety program/ISA documentation

Source	Citation	Comment	Response
	(g) Preliminary ISA	NEI recommends that the American Institute of Chemical Engineering (AIChE) terminology be employed ('preliminary Process Hazards Analysis') rather than 'preliminary ISA'	Comment no longer applies. NEI subsequently commented that the requirement to submit the preliminary ISA (or PHA) be deleted. That comment accepted by the staff
	(h) ISA Filing by Existing Licensees	NEI recommends that the term 'compliance plan' be replaced simply by 'program' in this subsection.	Agree in part. 'Plan' (not 'program') was adopted in place of 'compliance plan'
	(i) Management Measures	the eight measures appear overly prescriptive and should be relocated to ¶5.4.4 ('Management Measures') in the SRP as acceptable, 'possible' measures to provide the required assurance.	Agree in part. The prescriptive list was deleted from what is now 70.62(d). The topical areas were retained in a newly added definition of management measures.
		additional language should be added to assure the NRC that an item relied on for safety will have assurances of availability and reliability that are appropriate to the nuclear criticality risk it is designed to prevent or mitigate.	Agree. 70.62(d), on management measures now links directly to the performance requirements. Grading is permitted.
		NEI recommends that this sub-section be simplified to read: <i>"(d) <b>management measures.</b> Each licensee or applicant shall establish management measures to ensure that each item relied on for safety described in the ISA Summary will perform its intended function when needed. The assurance of availability and reliability of such an item relied on for safety may be graded to the risk it is designed to prevent or mitigate."</i>	Agree in part. Similar but slightly modified language was adopted into what is now 70.62(d). Definition of management measures was also added to 70.4
	(j) Unacceptable Vulnerabilities	term 'unacceptable vulnerabilities' be replaced by 'unacceptable performance deficiencies'	Agree. 'unacceptable vulnerabilities' replaced by 'unacceptable performance deficiencies' throughout

Source	Citation	Comment	Response
	(k) Definitions (§70.4)	<p>The following definition proposed by NEI is recommended for inclusion in §70.4 instead of that proposed in the December 1998 NRC posting:</p> <p>“ISA summary means a synopsis of the results of the ISA that succinctly describes the facility or its processes, identifies the disciplines of expertise and minimum qualifications of the individuals who performed the ISA and outlines the approach and methodologies used in performing it. The ISA summary identifies and describes those credible accident sequences, whose unmitigated consequences could exceed the consequences of concern in §70.60(b), the safety controls (or items relied on for safety) to mitigate the risk of such accidents to an acceptable level and the measures to ensure the availability and reliability of such controls. The ISA summary shall be placed on the docket and shall be updated annually by the licensee, but shall not constitute part of the license.”</p>	<p>Agree in principle. The current definition states: <u>Integrated safety analysis summary</u> means the document submitted with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety analysis and contains the information specified in §70.65(b). 70.65 lists of contents for the submitted ISA summary.</p> <p>The ISA summary will be updated within 90 days of a change which affects the summary. All other changes will be submitted annually.</p>
	<b>III. Comments on Nuclear Criticality Safety Issues</b> (a) Historical NCS Data	NEI recommends that the list of operational events not be incorporated in the license. An acceptance criterion could, however, be inserted into the ISA chapter of the SRP that would require an applicant to examine ten years of operational events in preparing the ISA.	Agree. This requirement has been removed from the latest rule language.
	(b) Controls vs. Control Systems	<p>NEI recommends that the term ‘set of controls’ or ‘control system’ be used throughout the rule to clarify the broader meaning of control. For example, §70.60(e), as amended by the December NRC modifications, should read:</p> <p><i>“(e) Each engineered or administrative control or control system necessary to comply...”</i></p>	Agree. “... or control systems” added in several places in the rule. An item relied on for safety could include a system of controls.

Source	Citation	Comment	Response
NEI Feb. 12, 1999, letter (042-0062) on the need for inclusion of a Backfit Provision in the Part 70 rule.		NEI believes that the 'modest increase/minimal or inconsequential cost' standard is worthy of further consideration in a proposed rule	Agree in Part. Even minimal increase/minimal cost items may be considered.
		NEI strongly recommends that the proposed rule include an immediately effective backfit provision.	Disagree. The staff's position is outlined in the response to the SRM.
		NRC's proposed use of a qualitative, non-monetary methodology to derive the safety benefit of a backfit modification is inconsistent with NUREG/BR-0058 Rev. 2 ('Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission'), which requires use of quantitative analyses to the maximum extent possible.	Disagree. If quantitative analysis is required, this would push backfit towards using PRA which NEI has historically been against for Part 70 licensees.
		provision should be immediately effective. It should require a documented, quantitative analysis of any proposed modification to demonstrate that the proposed backfit: (i) will increase the overall protection of the public health and safety, and (ii) will have a cost of implementation that can be justified by the increase protection the modification affords.	Disagree. See positions in backfit response to SRM.
		include a 'compliance exception' clause that would state that a backfit analysis would not be required if the NRC determines that a backfit modification is necessary to bring the facility into compliance with its license commitments or that it is needed to protect the health and safety of the public, common defense and security.	Agree in Part. Would implement if backfit is implemented.
Feb. 1, 1999, letter from OSHA		A rule that generically addresses chemical hazards at NRC-licensed facilities would preempt OSHA from enforcing any of its standards with respect to chemical hazards at these facilities, not only Process Safety Management but such things as respiratory protection, confined space entry, lockout/tagout, etc. The MOU may not reflect OSHA's current position.	
		Decommissioning: Most of the hazards involving demolition would be better addressed by OSHA.	
		Exposure limits should not permit exposures in excess of OSHA's PEL's.	

Source	Citation	Comment	Response
NEI March 2, 1999, (042-0069) comments on SRP Chapter 6, Chemical Process Safety", with redline/strikeout markup.	Cover letter	There are instances in which the SRP does not correctly reflect revisions to the Part 70 Rule or the consensus achieved at NRC public meetings.	Agree. Comment was made based on SRP text prior to revision to reflect new rule language that codified MOU.
		The draft SRP does not adequately address the third MOU principle ('chemical risks produced from plant conditions that affect the safety of radioactive materials').	Agree. Comment was made based on SRP text prior to revision to reflect new rule language that codified MOU.
		The SRP should also be clarified to state that NRC Staff review of chemical process safety will be limited to those higher-risk sequences identified in the facility's ISA Summary.	Disagree. The meaning of the term Higher-risk is not clear. NRC will review those sequences that could exceed the performance requirements.
		The SRP should focus the reviewer on assessing the adequacy of an applicant's license commitments to chemical process safety, rather than evaluating detailed, process-specific information against unduly prescriptive acceptance criteria.	Agree. Comment was made based on SRP prior to revision. Latest revision may resolve this concern
		topics that are addressed in other SRP chapters should be expunged from Chapter 6. For example, the entire §6.4.3.4 ('Continuing Assurance of Chemical Process Safety') which addresses the reliability and availability of items relied on for safety, should more appropriately be reviewed in SRP Chapter 11 ('Management Measures').	Agree in part. Clarified that the information does not need to be repeated in the application. The SRP refers the reviewer to the appropriate section unless there is an aspect particular to that technical discipline.

Source	Citation	Comment	Response
	Redline/strikeout mark-up of SRP Chapter 6 ('CHEMICAL PROCESS SAFETY')	- SEE MARK-UP FOR SPECIFIC COMMENTS -	Adopted as appropriate. SRP chapter 6 was totally re-written based on the new rule and on NEI's mark-up.
NEI 3/2/99 (042-0070) in response to OSHA questions		The NRC/OSHA MOU is, in our view, consistent with the statutory allocation of jurisdiction between the NRC and OSHA, and serves as a useful frame of reference for discussing these issues.	No response necessary. The comment is a statement of opinion and support for no changes.
		We did not intend to, nor do we believe that the NRC's suggested changes to the draft rule would, encroach in any way on OSHA's traditional authority over non-radiological chemical hazards at NRC licensed facilities.	No response necessary. The comment is a statement of opinion and support for no changes.

Source	Citation	Comment	Response
NEI letter (042-0077), 3/26/99 letter, on rule revisions	Definitions: Available and Reliable	Replace "analysis" with "assessment"	Disagree. This term has been used since the original rulemaking.
		Add "when needed" after "safety function"	Agree.
		Replace "ensure continuous" with "provide reasonable assurance of" in "ensure continuous compliance with the performance requirements of 70.61."	Disagree. "Ensure continuous" was kept because the licensee must meet the performance requirements of 70.61 at all times. The proposed change incorrectly implies that the regulation is simply a target or a goal and as revised would allow the licensee to be out of compliance with the 70.61. Same changes requested in 70.62(d).



Source	Citation	Comment	Response
	Definitions: Configuration Management	Delete “all”	Agree in Part. “All” deleted, but phrase “that might impact the ability of item relied on for safety to perform their function when needed” added to end of sentence.
		Replace “the site, structures... personnel” with “items relied of for safety”	Agree.
	Definitions: Controlled Site Boundary	Delete definition in its entirety.	Agree.
	Definitions: Critical Mass of Special Nuclear Material	Delete definition in its entirety.	Disagree. Despite NEI’s comment that the term is no longer used, it is used twice in the revision reviewed by NEI. These two areas are: 1) the title of Subpart H and 2) in §70.66. In §70.76, the reference has been removed and instead changed to reference “an applicant subject to Subpart H”
	Definitions: Deviation from Safe Operating Conditions	Delete Definition in its entirety.	Agree.
	Definitions: Integrated Safety Analysis	Replace “analysis” with “assessment” (3 occasions)	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Replace “site, structures... personnel that are” with “items”	Agree.
	Definitions: Integrated Safety Analysis summary	Replace “analysis” with “assessment” (2 occasions)	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Delete “in conjunction”.	Agree.
		Replace “informs the Commission...;and the evaluations for compliance with the performance requirements of §70.61” with “contains the information specified in §70.65(b)”	Agree.

Source	Citation	Comment	Response
	Definitions: Items relied on for safety	Add “or mitigate” after “prevent” and remove “or to mitigate their potential consequences” at end of sentence.	Disagree. An accident is not mitigated, but rather the consequences of the accident are what is mitigated.
		Add “that could result in non-compliance with the performance requirements in §70.61” to end of sentence	Agree. Added “However, this does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.”
	Definitions: Management measures	Replace “analysis” with “assessment” .	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion. However, deleted phrase “identified in the integrated safety analysis” to reduce original limited scope of definition, making comment no longer applicable.
		Replace “ensure” with “provide reasonable assurance that”	Disagree. Ensure was kept to be consistent with other regulatory language. The regulations must be met and the licensee’s must ensure that they are met. The reasonableness of the assurances provided is evaluated during the inspection and enforcement process.
		Replace “quality” with “safety” and Replace “systems” with “measures”	Disagree. Replaced “quality assurance systems” with “quality assurance elements” to make it clear that some of the items listed already relate to quality assurance.
	Definitions: New processes at existing facilities	Delete definition in its entirety.	Agree.

Source	Citation	Comment	Response
	Definitions: Preliminary process hazards analysis	Delete definition in its entirety.	Agree.
	Definitions: Unacceptable performance deficiencies	Add “management” before “measures”.	Agree.
		Delete “used to assure the items are available and reliable to perform their function when needed,”	Agree.
	70.60	Delete “decommissioning of facilities used for these activities”.	Agree. However, added new statement “The regulations in §70.61 through §70.74 do not apply to decommissioning activities performed pursuant to other applicable Commission regulations including §70.25 and §70.38 of this Part” to end of paragraph. This addition was necessary to clarify that the licensee must continue to follow current decommissioning regulations since decommissioning actions were specifically removed from Subpart H.
		Add “These regulations do not apply to Gaseous Diffusion Plants”	Agree in part. Will change to “Also, the regulations in §70.61 through §70.74 do not apply to activities that are certified by the Commission pursuant to Part 76 of this Chapter.”
	70.61(a)	Replace “demonstrate” with “evaluate”.	Agree.
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Add “its” after “§70.62,”	Agree.

Source	Citation	Comment	Response
	70.61(b)	Replace “demonstrated” with “determined”	Disagree. The licensees must demonstrate to NRC that they meet the requirements of the regulation. For the licensee to simply “determine” that they meet the requirement does not provide NRC with the information necessary to determine the adequacy of the licensee’s safety basis. No justification for this change was provided.
	70.61(b)(2)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “to any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
	70.61(b)(3)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “by any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
	70.61(b)(4)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “to any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
		Replace “Part” with “part”.	Disagree. As it is referencing the rule language, it is NRC policy to capitalize “Part.”

Source	Citation	Comment	Response
	70.61(c)	Replace “demonstrated” with “determined”.	Disagree. The licensees must demonstrate to NRC that they meet the requirements of the regulation. For the licensee to simply “determine” that they meet the requirement does not provide NRC with the information necessary to determine the adequacy of the licensee’s safety basis. No justification for this change was provided.
	70.61(c)(2)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “to any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
	70.61(c)(3)	Delete “outside the restricted area” and add “to a member of the public outside the controlled area...”	Disagree. Wording kept to be consistent with §20.2202(a)(2).
	70.61(c)(4)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “to any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
		Add “licensed” before “material” in last sentence.	Disagree. Not all chemical exposures covered under this regulation would be from licensed material; it may instead be associated with such material.
		Replace “Part” with “part”.	Agree. In this case, the word part is not referring to the rule.

Source	Citation	Comment	Response
	70.61(e)	Replace “ensure that each” with “provide reasonable assurance that” and change “its” to “their”	Disagree. Ensure was kept to be consistent with other regulatory language. The regulations must be met and the licensee’s must ensure that they are met. The reasonableness of the assurances provided is evaluated during the inspection and enforcement process. The proposed change incorrectly implies that the regulation is simply a target or a goal.
	70.62(a)(1)	Replace “that ensures that actions taken...and of the environment” with “consisting of appropriate management...when needed”.	Agree in part. Agree to modify statement that is requested to be deleted; however, NEI’s change improperly characterizes the safety program as management measures only whereas the safety program also includes process safety information and the integrated safety analysis. Therefore statement will be changed to “that demonstrates compliance with the performance requirements of §70.61.”
		Delete “the safety program, including”.	Disagree. This again improperly attempting to characterize the safety program as management measures only. To clarify this point, the final sentence was changed to state “The three elements of the safety program, namely process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.”
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(b)	Delete “compile and” and delete “a set of”.	Agree.

Source	Citation	Comment	Response
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(c)	Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(c)(1)	Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(c)(1)(i)	Replace “hazards” with “risks”.	Disagree. Although the use of risks is consistent with the MOU with OSHA, the intent of the statement is to identify the hazard so that one can evaluate the risk.
	70.62(c)(1)(ii)	Replace “hazards” with “risks”.	Disagree. Although the use of risks is consistent with the MOU with OSHA, the intent of the statement is to identify the hazard so that one can evaluate the risk.
		Replace “or” with “and”.	Agree.
	70.62(c)(1)(iii)	Replace “hazards” with “risks”.	Disagree. Although the use of risks is consistent with the MOU with OSHA, the intent of the statement is to identify the hazard so that one can evaluate the risk.
		Delete “(e.g., chemical, fire,...)”.	Agree.
	70.62(c)(1)(vi)	Replace “Part” with “part”.	Disagree. As it is referencing the rule language, it is NRC policy to capitalize “Part.”

Source	Citation	Comment	Response
	70.62(c)(1)	Add "The integrated safety assessment need not be docketed..."	Disagree. Although this intent will be stated in the statement of considerations, all submittals to NRC must be docketed; however, there is no requirement to submit the ISA and thus docketing should not be an issue.
	70.62(c)(2)	Replace "analysis" with "assessment" (3 places).	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(c)(3)(i)	Replace "6" with "twelve".	Disagree. No justification for change was provided. As existing licensees are already significantly involved in the development of this rule and ISAs at their sites, development of a plan within 6 months of issuance of the final rule should not be a significant burden.
		Add "unless otherwise specified by the conditions of..."	Disagree. This is unnecessary rule language as NRC expects all licensees to meet the time period provided.
		Replace "analysis" with "assessment".	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Delete "Pending the correction of unacceptable... adequate protection."	Agree in Part. The statement will be removed from this section as it is not directly relevant to other discussion in §70.62(c)(3)(i); however, it will be replaced in its entirety as a new item §70.62(c)(3)(iii).



Source	Citation	Comment	Response
	70.62(c)(3)(ii)	Replace "4" with "five".	Disagree. No justification for change was provided. As existing licensees are already significantly involved in the development of this rule and ISAs at their sites, development of a plan within 4 years after approval of the licensee's plan should not be a significant burden. (See next item)
		Replace "<effective date of this rule>" with "date of approval of the licensee's plan by the Commission".	Disagree. No justification for change was provided. As existing licensees are already significantly involved in the development of this rule and ISAs at their sites, development of an ISA within 4 years of issuance of the final rule should not be a significant burden.
	70.62(d)	Replace "safety program management measures" with "management measures" (2 places).	Agree.
		Replace "continuing" with "reasonable" in "establish management measures to provide continuing assurance of compliance with performance requirements of section 70.61".	Disagree. 'Continuing' was kept because the licensee must meet the performance requirements of 70.61 at all times. The proposed change incorrectly implies that the regulation is simply a target or a goal and as revised would allow the licensee to be out of compliance with the 70.61.
		Add "or control system" after "control" (3 places).	Agree.
		Add "items" before "relied on for safety".	Agree.

Source	Citation	Comment	Response
		Replace “ensure” with “provide reasonable assurance that”.	Disagree. Ensure was kept to be consistent with other regulatory language. The regulations must be met and the licensee’s must ensure that they are met. The reasonableness of the assurances provided is evaluated during the inspection and enforcement process. The proposed change incorrectly implies that the regulation is simply a target or a goal.
	70.64(a)	Delete “of the type listed in §70.60 of this part”.	Agree.
		Replace “or” with “. Each existing licensee shall ... in the”.	Agree.
		Add “that require a license amendment under §70.72” to end of 2nd sentence.	Agree.
		Replace “their process design and description” with “the new facility or process”.	Agree in Part. Modification was made to delete sentence in its entirety.
		Add new sentence “The baseline design criteria... or process.”	Agree in Part. New sentence added to state “The baseline design criteria shall be applied to the design of new facilities and new processes, but shall not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in §70.61.”
	70.64(a)(1)	Replace “established” with “developed”.	Agree.
		Replace “a quality assurance program” with “established management measures”.	Agree.
	70.64(a)(5)	Replace “hazards that may impact the storage, ... exposure to an individual from licensed material or” with “risks produced from licensed material... and exposure to”.	Agree in part. Removed phrase “exposure to” from NEI request but made all other modifications requested.
	70.64(a)(7)	Delete “,including reliable and timely... for safety.”	Agree.

Source	Citation	Comment	Response
	70.64(a)(8).	Add “Monitoring” and Replace “provide for” with “consider the need for monitoring”.	Disagree. To be consistent with §60.131, Instrumentation and Controls will remain separated from this item.
		Replace “ensure” with “provide reasonable assurance”.	Disagree. Ensure was kept to be consistent with other regulatory language. The regulations must be met and the licensee’s must ensure that they are met. The reasonableness of the assurances provided is evaluated during the inspection and enforcement process. The proposed change incorrectly implies that the regulation is simply a target or a goal.
		Replace “continued function and readiness” with “availability and reliability when needed”.	Agree in part. Changed to “availability and reliability to perform their function when needed.”
	70.64(a)(10)	Delete item 10 in its entirety.	Disagree. To be consistent with §60.131, Instrumentation and Controls will remain as a separate item. Further, the proposed merging of this item with item number 8 does not include the role of control systems.

Source	Citation	Comment	Response
	70.64(b)	Delete 1st sentence.	Disagree. However, the term “defense in depth” will be clarified through the use of a footnote which states “As used in §70.64, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents. “
		Replace “passive systems are selected over active systems” with “engineered controls or control systems are preferable to administrative controls or control systems” and replace “by reducing challenges... for safety.”	Agree in part. Sentence will now read “The design process shall incorporate, to the extent practicable: (1) preference for the selection of engineered controls over administrative controls to increase overall system reliability; and (2) features that enhance safety by reducing challenges to items relied on for safety.”
		Delete last sentence in its entirety.	Agree.
	70.64(c)	Replace “analysis” with “evaluation”.	Disagree. However, comment is moot since the section was deleted in its entirety.

Source	Citation	Comment	Response
		Add “that requires a license amendment under §70.72” before “shall.”.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(1)	Replace “satisfy, with incorporated margins for uncertainty,” with “address”.	Agree. However, comment is moot since the section was deleted in its entirety.
		Replace “§70.60” with “§70.61”.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(2)	Replace “analysis” with “evaluation”.	Disagree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(3)	Replace “analysis” with “evaluation”.	Disagree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(3)(i)	Delete “defense-in-depth strategy and”.	Disagree. However, comment is moot since the section was deleted in its entirety.
		Add “and” at end of item.	Disagree. “And” is implicit. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(3)(ii)	Delete item in its entirety.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(3)(iii)	Change to “ii”.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(4)	Delete item in its entirety.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(5)	Delete item in its entirety.	Agree. However, comment is moot since the section was deleted in its entirety.

Source	Citation	Comment	Response
	70.64(d)	Delete first sentence.	Agree. However, comment is moot since the section was deleted in its entirety.
		Add word “applicable” before “regulations.”	Agree. However, comment is moot since the section was deleted in its entirety.
	70.65(a)	Replace “a summary of the integrated...established to ensure”.	Agree in Part. Replaced “a summary of the integrated... and in the context of the performance requirements of §70.61” with “the integrated safety analysis summary and a description of the management measures.” This change should capture NEI’s comments while shortening the text by removing some text that is repeating already defined terms.
	70.65(b)	Replace “summary of the integrated safety analysis” with “summary” (2 occasions).	Agree in Part. Replaced “summary of the integrated safety analysis” with “integrated safety analysis summary” to use defined term.
		Delete “,” after “license”.	Agree.
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.65(b)(1)	Add “general” before “description”.	Agree.
	70.65(b)(2)	Add “general” before “description”.	Agree.

Source	Citation	Comment	Response
	70.65(b)(3)	Replace “each process” with “processes”.	Disagree. NEI did not provide a reason for the requested change; however, NEI is likely concerned about the level of detail to describe “each” process. To account for this concern, a definition for process “(defined as a single reasonably simple integrated unit operation within an overall production line)” was included to better define level of detail expected.
		Replace “integrated safety analysis including the theory of operation” with “and a general description of the types of accident sequences for each that could exceed the performance criteria of §70.61”.	Agree in Part. Replaced “integrated safety analysis including the theory of operation” with “integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to §70.62(c)(1)(i)-(iii) and a general description of the types of accident sequences.” The changes to NEI’s proposed text are to better define what is requested.
		Move “information that demonstrates...alarms in §70.24” to a new item (4).	Agree in Part. Text moved to new item (4) as requested but modified to state “information that demonstrates the licensee’s compliance with: the performance requirements of §70.61; the requirements for criticality monitoring and alarms in §70.24; and, if applicable, the requirements of §70.64.”
	70.65(b)(4)	Change to 70.65(b)(5).	Agree.
		Delete “integrated safety analysis” before “team”.	Agree.
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.

Source	Citation	Comment	Response
	70.65(b)(5)	Delete item in its entirety.	Agree in Part. Original item(5) deleted, but intent of item moved to additions in new items (3) and (4) of this section.
	70.65(b)(6)	Replace item in its entirety with “for the purpose of this integrated safety assessment summary... to understand their function in relation to the performance requirements of §70.61”.	Agree in Part. Modified in entirety to state “a list briefly describing all items relied on for safety which are identified pursuant to §70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of §70.61;” A list of items is essential to NRC’s determination that the ISA summary provides an adequate safety basis for licensing the facilities.
	70.65(b)(7)	Delete (7) in its entirety.	Agree.
		Add new item (7) that states “a description of the management measures applicable to such items relied on for safety”.	Disagree. This requirement is redundant with the requirement in 70.65(a) that requires a description of management measures to be included with the application. The intent is not to require the licensee to identify what management measures apply to each item relied on for safety, but rather to describe the programs used in more general terms so as to not be burdensome to applicants.
	70.65(b)(8)	Replace “material” with “materials”.	Agree. This item becomes item (7).
	70.65(b)(9)	Replace “item” with “items” (2 instances) and replace “is the” with “identifies”.	Agree in Part. Replaced first occurrence, but did not replace second since a “sole item” is being referred to. This item becomes item (8).
		Replace “is the” with “identifies”.	Agree in Part. Modified item to start “a descriptive list that identifies all items relied on for safety that are the sole item...”



Source	Citation	Comment	Response
	70.65(b)(10)	Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion. This item becomes item (9).
	70.72(a)(3)	Add “including any necessary training/retraining before operation”.	Agree; however, replaced “/” with “or”.
	70.72(a)(4)	Delete item in its entirety.	Agree.
	70.72(a)(7)	Replace “analysis” with “assessment” (2 instances).	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion. Note: this item becomes (6).
	70.72(c)	Delete item in its entirety.	Agree.
	70.72(d)(1) (Option1)	Replace item in its entirety with “does not: (i) create new types of accidents... has no prior experience”.	Agree in Part. Item replaced with “does not: (i) create new types of accident sequences, that unless mitigated or prevented, would exceed the performance requirements of section 70.61 and that have not previously been described in the integrated safety analysis summary; or (ii) use new processes, technologies, or control systems for which the licensee has no prior experience.” What is meant by the term “type” is described by a footnote.
	70.72(d)(2) (Option 1)	Replace “equivalent” with “a comparable”.	Agree in Part. Instead replaced” an equivalent replacement” with “at least an equivalent replacement of the safety function.” This change is to better define the fact the better replacements are acceptable; however, changes that reduce safety require pre-approval.

Source	Citation	Comment	Response
		Replace “item relied on for safety that is listed” with “any control or control system described”.	Disagree. NEI’s change in this section was to correspond to their change in §70.65(b)(6) which staff disagreed with. Since no change was made to that section, the text in this section remains the same to remain consistent with the fact that items relied on for safety are provided in the ISA summary.
	70.72(d)(3) (Option 1)	Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Replace “exceess” with “exceeds”.	Agree.
	70.72(e) (Option 1)	Replace (d) with (c).	Agree. However, comment is moot since the section was deleted in its entirety.
		Replace “[“ and “]” with “<“ and “>”, respectively.	Agree. However, comment is moot since the section was deleted in its entirety.
		Replace “analysis” with “assessment”.	Disagree. However, comment is moot since the section was deleted in its entirety.
	70.72(f) (Option 1)	Replace “(e)” with “(d)” and replace “(d)” with “(c)”.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.72(g)(1)	Replace “analysis” with “assessment” (2 instances).	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.

Source	Citation	Comment	Response
		Replace “within 90 days of the change” with “annually”.	Disagree. The ISA summary is intended to be a living document and therefore must be updated on a frequent basis. NRC staff needs to have a current safety basis on the docket in order to understand the facility, facility safety, and the changes made to the facility. Although Part 50 requires annual updates, the change process associated with that regulation is must more restrictive and NRC maintains knowledge about the facility and the changes to the facility through the change process. The change process proposed for Part 70 is less restrictive and allows the licensees to make changes with out NRC pre-approval. However, because of the flexibility allowed here, the ISA summary must be updated more frequently.
	70.72(g)(3)	Replace “process safety information, integrated safety analysis, or management measures” with “integrated safety assessment summary”.	Agree in Part. Replaced “process safety information, integrated safety analysis, or management measures required by section 70.62” with “records required by section 70.62(a)(2)”. Also added word “brief” before “summary”.
		Replace “every 6 months” with “annually”.	Agree in Part. Changed “every 6 months” to “every 12 months.”
	70.72(h)	Replace in item in its entirety with “If a change covered by §70.72 is made, the affected onsite documentation shall be updated promptly.”	Agree.
	70.72(i)	change “(d or e)” to “(c or d)”.	Agree.
	70.73	Delete 2nd sentence.	Agree.

Source	Citation	Comment	Response
	70.74(a)		Replaced references to “section (c) in Appendix A to Part 70” with “§70.50(c)(1)” to be consistent with NEI’s comments in Appendix A.
	70.74(b)		Replaced references to “section (d) in Appendix A to Part 70” with “§70.50(c)(2)” to be consistent with NEI’s comments in Appendix A.
	Appendix A (a)(1)	Replace “unintended” with “inadvertent”.	Agree.
	Appendix A (b)(1)	Move (b)(1) to (a)(4).	Agree in part. Moved, but modified to state: “An event or condition such that no items relied on for safety, as documented in the Integrated Safety Analysis summary, remain available and reliable, in an accident sequence evaluated in the Integrated Safety Analysis, to perform their function: (i) in the context of the performance requirements in §70.61(b) and §70.61(c), or (ii) prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).
	Appendix A (b)(2)	Delete item in its entirety.	Disagree. The purpose of this item is to determine if accidents frequencies are classified correctly so that if a licensee takes credit for infrequency and the occurrence of the deviation is frequent, NRC is notified of the potential problem in the analysis technique. The item has also been relocated as item (5).
	Appendix A (b)(3)	Add “,was improperly analyzed” after “was not analyzed”.	Agree.
		Delete first instance of “in the Integrated Safety Analysis”.	Agree.

Source	Citation	Comment	Response
		Replace "Analysis" with "Assessment".	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	Appendix A (b)(4)	Replace "has affected or may have affected the intended safety function and reliability of one or more items relied on for safety" with "affected the availability and reliability of one or more items relied on for safety and could have resulted in a failure to meet the performance requirements of §70.61."	Disagree. The intent is to also have external events reported that may also have affected items relied on for safety but didn't because either possible problems had not yet been detected or were mitigated or prevented by previously unreported items that were relied on to remain safe. Did, however, replace "availability and reliability" with "availability or reliability".
	Appendix A (b)(6)	Replace "an" with "a sole".	Agree. However, comment is moot as this item was deleted.
		Delete "This includes... perform the same safety function."	Agree. However, comment is moot as this item was deleted.
	Appendix A (b)(7)	Replace "restricted" with "controlled area".	Disagree. Wording kept to be consistent with §20.2202(a)(2). However comment is moot because item modified in its entirety to state "Loss or degradation of items relied on for safety that results in failure to meet the performance requirement of 70.61".
	Appendix A (b)(8)	Delete item in its entirety.	Disagree. However, item moved to new item (c) of Appendix A. NRC would like to be aware of communications which may result in inquiries from outside sources.
	Appendix A (c)	Delete item and all subitems in their entirety.	Agree.
	Appendix A (d)	Delete item and all subitems in their entirety.	Agree.

## Comments Posted on Web Site “Threads” Page

Date	Author/ Affiliation	Topic	Subject	Comment	Response
Jan. 6, 1999	Steve Schilthelm/ BWXT	Separating the performance requirements from the descriptive requirements	70.62(c)(3) Integrated Safety Analysis Revalidation	an enhanced approach to change management which uses ISA evaluation techniques and team concepts with qualified reviewers would provide greater confidence in the continuing validity of the ISA results and would eliminate the need for periodic revalidation.	Agree. Revalidation of ISA was deleted as unnecessary, since the 70.72 process governs the facility changes and updating of safety program/ISA documentation
				BWXT believes the focus should be on quality configuration management and maintenance of a valid ISA rather than periodic revalidation and that this section should be deleted.	Agree. Revalidation of ISA was deleted as unnecessary, since the 70.72 process governs the facility changes and updating of safety program/ISA documentation
			70.4 Controlled Site Boundary	It appears that 10CFR20 definitions are adequate and that the ISA consequence criteria should be applied at the Controlled Area Boundary as defined in 10CFR20.	Agree in part. 70.61(f) was added to use the controlled area definition consistent with Part 20. However, in recognition that activities unrelated to licensed activities occur in the controlled area of some Part 70 facilities, some conditions were added.
			70.62(d) Management Measures	BWXT supports the concept of management measures as presented. Section (d)(6) however, implies that a QA program be implemented in addition to other management measures in 70.62(d), some of which are elements of a QA program. Section (d)(6) appears to be redundant and unnecessary and should be deleted.	The comment no longer applies because the list was deleted. In the definition management measures, the term “other QA elements” is used. QA and management measures are not synonymous. Management measures, could, for example, include a condition on operations in the event of a system's failure.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.4 Integrated Safety Analysis Summary	BWXT supports use of this terminology. This definition places the ISA Summary as part of the license application. Although this is contrary to Industry's position, BWXT believes the ISA Summary could be part of the license application (as BWXT is currently doing with a two part license) as long as it is clearly stated in the rule that changes to the process and the ISA Summary do not require license amendment. This would require some minor revision to this definition.	Agree in part. This terminology reflects the concept of the rule. 70.4 defines the ISA summary and states it will be submitted with the license application. Section 70.65 states that the summary will not be part of the license but will be on the docket. 70.72 specifies the changes that do not need pre-approval.
			70.72	To support the BWXT position on ISA Summary being part of the license application, the draft proposed language in 10CFR70.72 would be revised in order to clearly state when a license amendment is required for changes to the ISA Summary (Part 2 of the license). 70.72 should be consistent with the 12/1/98 SRM in that only "those few significant changes that currently would require license amendments" would require license amendments in the future.	Agree. 70.72 was revised as stated above. and does meet the intent of the SRM by requiring pre-approval for the most significant changes which inconsistent with past practices.
Feb. 2, 1999	Thomas P. McLaughlin LANL	Criticality safety	General	I'm optimistic that the NEI's proposed revisions will be adopted essentially as is by the NRC.	Disagree. Much of NEI's comments were adopted; but not all and not in the form that NEI requested.
				I would also hope that the discussions that are now documented in the transcripts of these public meetings could be retained as evidence of the understanding and interpretation of the intent and flavor that the NRC intends for the words in the Rule and SRP.	Agree. Transcripts and letters received by NRC related to this rulemaking will be in the public record.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			Double Contingency Principle (DCP)	Section 4.1.2 of ANS-8.1 is the overriding SHALL statement while 4.2.2(DCP) is simply a SHOULD statement. It is essentially unanimous among the experienced practitioners nationwide that the NRC, and now the DOE, are misguided in their attempts to "better?" control criticality risks by making the DCP a SHALL statement.	Agree. The new, separated performance requirement for criticality, 70.61(d), uses language similar to section 4.1.2 of ANS-8.1 (the "shall" statement) and DCP is defined similar to section 4.2.2 of ANS-8.1 (the "should" statement).
			NCS Limits(Section 5.4.5.2)	these additional limit definitions could add significant paperwork and reduce operational flexibility but not enhance real safety.	No longer applicable. The NCS limit definitions have been removed from the SRP Chapter.
				It is misguided and likely dangerous to attempt to specify either a single, subcritical k-eff, such as 0.95, or a single delta k-eff such as 0.02, that is intended to be applied to all situations	No longer applicable. The quantification of subcritical limits has been replaced by Margin of Safety for Subcriticality.
Feb. 3, 1999	James S. Baker/LANL	Criticality safety	I urge the NRC to carefully review and act up the recommendations made by NEI and Dr. McLaughlin relative to the proposed 10CFR70 revisions.		Agree. NRC has reviewed and acted upon comments provided.
			The ANSI/ANS-8 series of standards provide terse, yet comprehensive guidelines for the practice of nuclear criticality safety (NCS). Deviating from these guidelines will almost always lead to wasted time and effort, and a decrease in real safety.		Agree in Part. Some ANS-8 standards are not completely clear and in such cases, NRC has attempted to provide an interpretation for NRC use.
Mar. 17, 1999	Steve Schilthelm/BWXT	BWXT comments on 3/1 draft of 10CFR70	70.4 New Processes at Existing Facilities	The definition should only include Facility Level changes so that the requirements of 70.64 (c) & (d) are consistent with Commission directives in SECY 98-185.	Agree. Comment does not apply anymore. Consistent with a subsequent NEI comment, this definition was eliminated and 70.72 is used to identify the new processes at exiting facilities that need the application of 70.64 BDCs



Date	Author/ Affiliation	Topic	Subject	Comment	Response
				<p>The value of 70.72 should also be considered given that 70.64 appears to define when a license amendment is required.</p>	<p>Disagree. 70.64 requires application of BDC's to <u>new processes</u> (i.e., major changes). 70.72 could require pre-approval of changes that are not necessarily new processes and would therefore not require application of the BDCs.</p> <p>70.72 is important to define changes to the facility 70.75 is for new facilities and new processes.</p>
				<p>BWXT has reviewed Facility, System, and Component Level changes initiated during 1998 under SNM-42. ... an additional 30 license amendments would have been required in 1998 under the proposed rule language.</p>	<p>Disagree. This was not the intent. Perhaps the meaning of "new process" was misunderstood. In any event, the subsequent changes based on the NEI 3/26/98 comments obviate this comment. The definition was deleted and 70.72 is used to identify the new processes at exiting facilities that need the application of 70.64 BDCs</p> <p>70.72 was revised to attempt to limit the number of licence amendment required to approximately the number required prior to rule making</p>

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.64 (c)(4)	providing a Preliminary Process Hazards Analysis to NRC prior to construction is an exercise which appears to have no function in the licensing process. ... an open-ended regulatory requirement is inappropriate.	Agree that Preliminary Hazards analysis as a pre-licensing tool, not a tool for the licensing process. See also response to NEI 3/26 comments on Preliminary PHA submittal.
			70.65(b)	This section implies ALL license amendments require an ISA summary. There are, however, administrative and programmatic commitments in the license application (e.g., Organization) which do not impact the ISA Summary. Flexibility should be provided for these types of amendments.	Agree. Section was revised to indicate not all amendments require ISA summary information.
			70.65(b)(1-10)	The ISA Summary content requirements appear to be expanded even beyond those presented in the draft SRP. This level of information in the ISA Summary will provide more detail than the review can digest and may mask the forest with the trees. Suggest a higher level summary.	Disagree- The revised ISA summary contents were modeled after the suggested ISA summary submitted by NEI in the December 3 and 4 <sup>th</sup> meeting. The level of detail has been reduced from the previous draft rule and is at a level appropriate to provide useful information to NRC without being burdensome to the industry.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.65(b)(10)	These terms can be discussed in qualitative terms but the decision regarding where a particular event, failure, or occurrence fits in these terms MUST be based on the experience and judgement of qualified ISA team members. ... Attempts to define these terms implies a level of quantitative assessment that is simply not practical or necessary at fuel facilities.	Agree - this comment refers to the requirement in the ISA summary for the licensee to define how they used the terms likely, unlikely and highly unlikely in their analysis. It is up to the licensee to determine how best to define these terms and the determination concerning which category an event falls into should be based on the licensee's experience and judgment. However, the rule requires that certain events be shown to be unlikely or highly unlikely. If the license does not define these terms they can not then prove that they meet the rule. These definitions must be included in the ISA summary.
			70.72	Neither Option 1 or 2 of paragraph (d) is consistent with commission directive in SECY 98-185 which limits the types of changes requiring submittal for license amendment to "those few significant changes that currently would require a license amendment."	Disagree. Only one option, Option 1 remains in the rule. Option 2 has been removed. The staff believes Option 1 is consistence with Secy 98-185.
				It is also unclear how these options relate to the definition of New Processes at Existing Facilities and the requirements 70.64(c) & (d).	Rule revised to delete definition and cross reference §70.64 and §70.72

Date	Author/ Affiliation	Topic	Subject	Comment	Response
				NRC should limit the requirements for license amendments to facility level changes and changes to authorized activities. This would be consistent with Commission directives not to lower the license amendment threshold. 70.64(c) & (d) and 70.72 should be revised to clearly state.	Agree. These sections have been revised to incorporate this.
			70.72(g)	nearly every change to process safety information will require revision of the ISA Summary.	Disagree. The content of the ISA summary does not include detailed process information, and the level of detail in the summary determines the number of updates required. In addition, because the ISA and ISA summary are "living" documents changes to the information contained in these documents should be updated regularly.  The number of changes which would require a change to the ISA summary is determined by the level of detail the licensee chooses to put in the summary
				given the level of detail in the ISA Summary, the 6-month notification of change to process safety information seems unnecessary... Notification of changed process safety information should be deleted.	Agree - The requirement to submit a brief summary of all changes to records required by 70.62(a) has been revised to an annual update, This would include a summary of changes to process safety information.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
				BWXT recommends the ISA Summary be updated annually, or with each license amendment.	Disagree- The ISA summary is to be a living document which contains relatively current information. This information is to be used in licensing, inspection and emergency response. A one year update period or greater is not sufficient.
Mar. 24, 1999	Burton Rothleder/ DOE	References and terminology in the Criticality SRP Chapter		1. Update: ANSI/ANS-8.1-1998 is the latest revision of this endorsed ANSI/ANS standard.	Agree. However, NRC has not yet endorsed the 1998 revised standard ; this should be made in the next revision of NRC's Regulatory Guide.
				2. Correction to ANSI/ANS-8.6: In section 5.3, the "i.e." should be "e.g." This is not merely a typo correction since the used of "i.e." tacitly omits (n,2n) reactions as sources of neutrons. By endorsing this ANSI/ANS standard, I think that this error should be noted as part of the SRP	Disagree. The endorsement correction, if appropriate, should be made in the next revision of NRC's Regulatory Guide endorsing the standard rather than the SRP.
				3. Section 5.4.3.1: In section 5.4.3.1, paragraph 6.b., the sentence should read "... <i>deterministic computer codes, or stochastic computer codes which ...</i> " I have replaced "probabilistic" with "stochastic" in order to avoid confusion with PRA codes.	Agree in Part. The words have been changed in the SRP to accurately reflect the meaning.
3/29/99	Thomas P. McLaughlin/ LANL	Comments on Draft NUREG-1520 , Chapter 5, Nuclear Criticality Safety (NCS) rev. March 15, 1999	General:	If the ISA is analogous to the SAR in the DOE, then the ISA should be the place for a Design Basis or Worst Credible criticality accident scenario in order for the applicant to demonstrate that criticality accidents are very unlikely and that they have essentially zero off-site consequences. I.e., they are worker safety issues and not a threat to the public or the environment.	Disagree. The ISA is expected to evaluate all potential accidents and those with a potential to exceed the performance criteria are to be reported in the ISA summary to NRC -- not just the bounding evaluations.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
				Individual criticality safety evaluations (CSE) should be where each separate process is documented, not in the ISA.	Disagree. The ISA is expected to include the equivalent of the CSE.
				Perhaps more so in the DOE world, but operations are continually changing and new ones are being added such that requiring regulatory approval except for those new or changed operations which represent a greater risk than that currently in the ISA, is not justified.	Disagree. The change process only requires pre-approval for certain changes as listed in 70.72.
				Similarly, the CSE is where the justification for active vs passive controls should be justified.	Agree. Because the ISA is expected to include the equivalent of the CSE, this justification would also be in the ISA.
				There is an over-emphasis on the Double Contingency Principle to the detriment of the control of criticality risks.	Disagree. The SRP Chapter makes it clear that there are alternatives to double contingency protection.
			5.4.1 (6) and repeated in 5.4.2 (1)(d)	"..... <i>take no further action</i> ....." This seeming prohibition to not allow risk-reducing actions is inconsistent with the ANS-8 standards and the philosophy implicit in section 5.4.3.3 (8) - " <i>.....because shutting down certain processes, even to make them safe, may carry a larger risk</i> ....."	Disagree. The SRP Chapter is consistent with the industry understanding that only analyzed and approved NCS actions should be taken.
			5.4.2 (3) (b)	"..... <i>weekly walkthroughs of all operating</i> ..... <i>all operating areas should be reviewed at least every two weeks</i> ...." This frequency is far beyond that of most, if not all, DOE regulated facilities and is not supported on the basis of performance-based and risk-informed regulation . A commitment to walkthroughs based on performance and risk would be consistent with DOE practices.	Disagree. Although this is industry practice, the SRP allows grading to justify other frequencies based upon the ISA evaluation.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			5.4.3.1 (3)(a)	Reference to, and a commitment to have copies of, appropriate reports should be sufficient . Otherwise it is unnecessary duplication.	Disagree. It is necessary for the reviewer to have a summary of the methodology in order to ensure that the applicant is using the methodology appropriately.
			5.4.3.1 (3)(f)	"..... <i>plant specific benchmark experiments</i> ....." is an unattainable ideal . If the intent is to require that the benchmark experiments chosen for code validation cover, to the extent available, the credible ranges of the process parameters, then that is realistic.	Agree. If the plant specific information exists, the applicant is expected to use it.
			5.4.3.1 (3)(i)	"..... <i>a verification process</i> ....." What does this mean?	Clarification. It means that the process used to determine that the methodology chosen is appropriate.
			5.4.3.1 (4) all subparts	This section is duplication of the prior subpart but with a different application . I suggest that the applications (headings) be combined and then the body would not have to be repeated.	Disagree. The two subparts havd different functions and different requirements. One requires information for the application, the other information for the site.
			5.4.3.1 (6) (c & d)	Where are "NCS safety limits" and "NCS operating limits" defined? Can they be one and the same as they are at most, if not all DOE facilities?	Clarification. Failure limits are where you fail, safety limits are where the analysis determines you are safe, and operating limits are set below the safety limits to ensure that you operate safely.
			5.4.3.2 (3)	"... <i>provide justification in the ISA</i> ." This should be a part of a CSE, not the ISA.	Disagree. The CSE is part of the ISA.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			5.4.3.2 (6)	"..... <i>credible abnormal conditions</i> ...." Certainly mass is the most common controlled parameter and yet it would generally not be considered "incredible" that a mass limit be violated, i.e., it would be considered credible . Thus the applicant could not meet this requirement.	Agree. Mass limit violation is a credible abnormal condition and by analyzing the scenario to its conclusion, you will have maintained the Controlled Parameter and met the SRP requirement.
			5.4.3.2 (9 & 10)	The numerical values (45%, 75%, 85%, 90%) have no basis in consensus standards or other recognized criticality documents. They should be deleted as they can only lead to a false sense of risk control. For example, ".... <i>When double batching is possible</i> ..." it would generally be also true that triple, quadruple, etc . batching is possible.	Disagree. These values are found in current licenses based on industry data from experiments.
			5.4.3.2.(12) (a)	".... <i>the SNM is segregated by enrichment</i> ." Why would it be unacceptable for the applicant to have assumed in the CSE that the highest credible enrichment was always present?	Agree. It would be acceptable for the applicant to assume the highest credible enrichment in the CSE.
			5.4.3.2 (13) (a)	The " <i>one foot</i> " restriction has no technical basis; it should be deleted.	Disagree. This is only a recommendation and not a requirement.
			5.4.3.2 (15) (b)	" <i>High concentrations</i> " needs to be defined.	Disagree. The intent of the term is different depending upon what process is being used.
			5.4.3.3 (3) (a)	".... <i>shall be required in each area</i> ...." This unilateral requirement does not allow for competing risks, or likelihoods that are judged to be in the incredible range, to be considered.	Disagree. This is part of the Rule itself and therefore a requirement.



Date	Author/ Affiliation	Topic	Subject	Comment	Response
			5.4.3.4	The repetition of the ANS-8 standards as requirements seems unnecessary.	Disagree. This is not repetition, but where the applicant commits to using the standards as an acceptable approach.
			5.4.3.4 (8)	I am not aware of a definition for " <i>administrative k-eff margins</i> ", but in general each process will have different margins of subcriticality and each will be highly judgmental based on the chosen conditions of analysis . These should be approved by line management and documented in the CSE . As stated under General, such information should not be in the ISA or otherwise require pre-approval outside of line management within the company.	Disagree. This value is pre-approved by NRC. For a particular process, the applicant may choose to use a higher margin which would be documented and approved by the applicant's management.
			5.4.3.5	This is another example of putting the recommendation, ANS-8.1, section 4.2.2, ahead of the requirement, section 4.1.2.	Disagree. This is part of the Rule itself and therefore a requirement.
			5.4.3.6 (3) (b)	Again, an over- and misleading-emphasis on Double contingency is evident.	Disagree. Double Contingency Protection is listed as an acceptable method, but not required.